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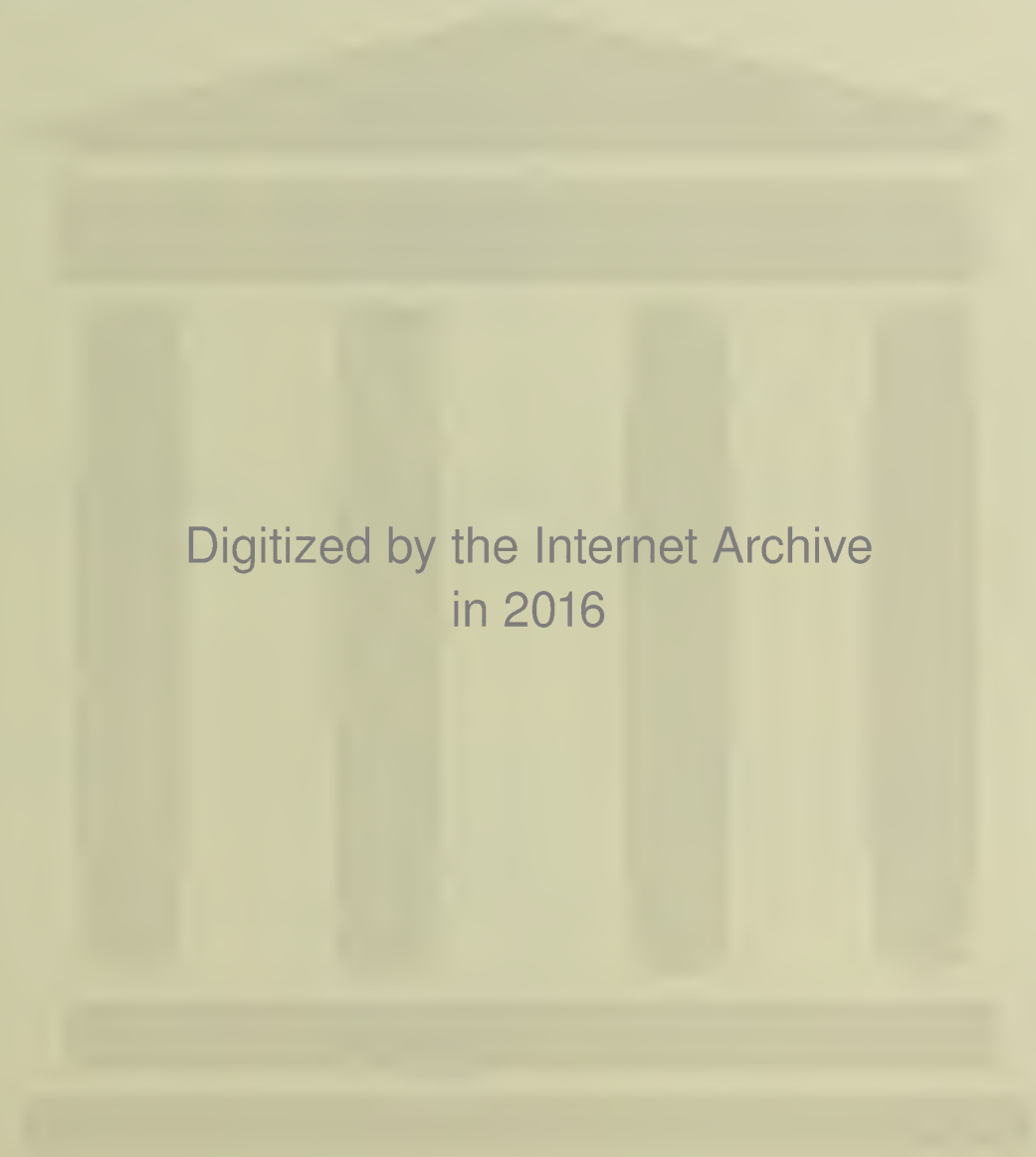

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CONTENTS

7 PRESIDENT'S PAGE
Are We a Self-Serving Group?

11 MEDICAL ETHICS

17 CURRENT MANAGEMENT OF SPONTANEOUS PNEUMOTHORAX
Festus B. Dada, M.D.
Allen L. Davies, M.D.

23 MEDICAL CLASSICS
MEMOIRE SUR LA FERMENTATION APPLEE LACTIQUE
David Platt, M.D.

29 EDITORIALS
National Cholesterol Education Program
Michael F. Stillabower, M.D.
Industrial Medicine and Community Doctors
William D. Shellenberger, M.D.
The Death of Benjamin Rush
Bernadine Z. Paulshock, M.D.

35 IN BLACK AND WHITE

39 PROCEEDINGS OF THE HOUSE OF DELEGATES, 1987: PART I
Medical Society of Delaware

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CONTENTS

67 PRESIDENT'S PAGE
Dover or Bust

69 OTITIS MEDIA: AN OVERVIEW OF CURRENT TREATMENT
Robert L. Witt, M.D.

73 WOMEN DOCTORS FROM JOHNS HOPKINS
Jo Ann Rosenfeld, M.D.

77 MEDICAL ETHICS

81 EDITORIALS
Negligence in Psychiatric Practice
V. Terrell Davis, M.D.
The Prescribing Habits of Delaware's Physicians
Bernadine Z. Paulshock, M.D.

89 IN BLACK AND WHITE

93 PROCEEDINGS OF THE HOUSE OF DELEGATES, 1987: PART II
Medical Society of Delaware

127 BOOK REVIEWS

132 DEATHS
Guido Ascanio, M.D.
Francis W. Godwin, M.D.
Charles M. Moyer, M.D.

133 IN BRIEF

Entered as second-class matter June 28, 1929 at the Post Office at Wilmington, Delaware, under the act of March 3, 1879. Issued monthly. Second class postage paid at Wilmington, Delaware. Copyright 1988 by the Medical Society of Delaware. Indexed in "Hospital Literature Index" and "Index Medicus." Available through University Microfilms. The "Delaware Medical Journal" does not hold itself responsible for statements made by any contributor or advertiser. POSTMASTER: Send address changes to "Delaware Medical Journal," 1925 Lovering Avenue, Wilmington, DE 19806. Subscription price: $15.00 per year in advance. Single copies $2.00.

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SPECIAL PEDIATRICS ISSUE
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CONTENTS

141 PRESIDENT'S PAGE
It's Everybody's Job

145 SPECIAL REPORT: THE WVMI PRO AND DELAWARE PHYSICIANS
William H. Duncan, M.D.

151 FEEDING THE LOW BIRTH WEIGHT INFANT
Mary Lavelle Spear, B.S.N.
Michael L. Spear, M.D.

159 A MULTIDISCIPLINARY APPROACH TO DEVELOPMENT DELAY IN HIGH RISK INFANTS
Nadia de Yanez, M.D.

165 MANAGEMENT OF CLOSED HEAD INJURIES IN CHILDREN
Michael Alexander, M.D.

169 PEDIATRIC ONCOLOGY: THE TEAM APPROACH AT THE MEDICAL CENTER OF DELAWARE
Rita S. Meek, M.D.

181 MEDICAL ETHICS

185 EDITORIALS
Spotlight on the Guest Editor
The Evolution of Pediatrics in Delaware
Michael L. Spear, M.D.
The Role of Subspecialists in a Community Practice Setting
Robert A. Doughty, M.D., Ph.D.
Pediatric Intensive Care
Michael E. Norman, M.D.
Handicapped Children: There Is Progress!
Ted E. Chronister, M.D.
You've Come a Long Way, Pediatrics
Maurice Liebesman, M.D.
Pediatric Nursing: Lessening the Emotional Trauma
Jacqueline W. Levett, R.N., M.S.N.
Cheers for Dr. Spear
Bernadine Z. Paulshock, M.D.

201 DELEGATE'S REPORT: 1987 INTERIM MEETING OF THE AMA HOUSE OF DELEGATES
Daniel A. Alvarez, M.D.

203 DEATHS
Martin B. Pennington, M.D.

207 IN BRIEF

203 COVER
Courtesy of Douglas Bugel

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CONTENTS

217 PRESIDENT'S PAGE
The Pitfalls of Peer Review

223 THE DILEMMA OF THE NURSING SHORTAGE
John M. Levinson, M.D.

231 SPECIAL REPORT: THE STATE OF PEER REVIEW IN DELAWARE TODAY
Victor Battaglia, Esq.

241 VIEW BOX
Intermittent Torticollis
Leslie E. Grissom, M.D.

245 MEDICAL ETHICS

247 EDITORIALS
The Pendulum's Arc: A Lesson For Today's Physician
Edward R. Sobel, D.O.
Integrating the Delaware Hospital: Does Anyone Remember?
Bernadine Z. Paulshock, M.D.
On the Diagnosis and Prevention of Bilateral Gluteal Hypermalacia Atrophicans Syndrome (Or Gallup Poll Disease)
Maurice Liebesman, M.D.

253 IN BLACK AND WHITE

255 LETTERS TO THE EDITOR

259 DEATHS
Walter L. Bailey, M.D.
Harry A. Carl, M.D.

261 BOOK REVIEWS

267 IN BRIEF

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CONTENTS

279 PRESIDENT'S PAGE
Arbitration — A Rational Alternative?

285 CARDIAC DOPPLER ECHOCARDIOGRAPHY PRINCIPLES AND APPLICATIONS
Christopher H. Wendel, M.D.

301 SPECIAL REPORT: DOCTOR-PATIENT ARBITRATION:
A PROPOSAL WHOSE TIME HAS COME
Francis S. Babiarz
Phillip B. Bartoshesky
Victor F. Battaglia
Jeffrey S. Marlin
Wayne A. Marvel
Roger Sanders
Mary Pat Trostle

307 THORACIC OUTLET SYNDROME: A THERAPEUTIC APPROACH BASED ON 115 CONSECUTIVE CASES
Allen L. Davies, M.D.
William Messerschmidt, M.D.

313 MEDICAL LEGAL CASE CONFERENCE: THE DOCTRINE OF INFORMED CONSENT
David E. Raskin, M.D.

317 MEDICAL ETHICS

321 EDITORIALS
Is Courtesy Old Hat?
Carl Glassman, M.D.
Common Diagnostic Tests: The Book and the Problem
Bernadine Z. Paulshock, M.D.
The "Crack" in the Emergency Room Door
Daniel G. Sayers, M.D.

329 IN BLACK AND WHITE

333 IN BRIEF

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C O N T E N T S

349 PRESIDENT'S PAGE
Protected Peer Review

351 MEDICAL GRAND ROUNDS:
OLD PEOPLE AND SURGERY
Herbert J. Keating, III, M.D.

363 RENAL FUNCTION AND DISEASE
IN THE ELDERLY
Laurence H. Beck, M.D.

371 PSYCHIATRY AND THE ELDERLY: DIAGNOSIS,
TREATMENT, AND MEDICAL/ETHICAL
DILEMMAS
David E. Raskin, M.D.

375 THYROID DISORDERS IN THE ELDERLY
William L. Jaffee, M.D.

379 HEALTH CARE OF THE ELDERLY: INFINITE
PROMISE IN A WORLD OF LIMITED RESOURCES
Senator William V. Roth, Jr.

385 MEDICAL ETHICS
Is Medical Ethics a Tradition and Ideal
Without a Future?
Edmund D. Pellegrino, M.D.

389 EDITORIALS
Introduction: The Newest Specialty
Herbert J. Keating, III, M.D.
Taking Care of the Well Elderly
Herbert J. Keating, III, M.D.
The Gray Boomers
Bernadine Z. Paulshock, M.D.
The State of The Art
Alvan R. Feinstein, M.D.

247 ABOUT THE COVER

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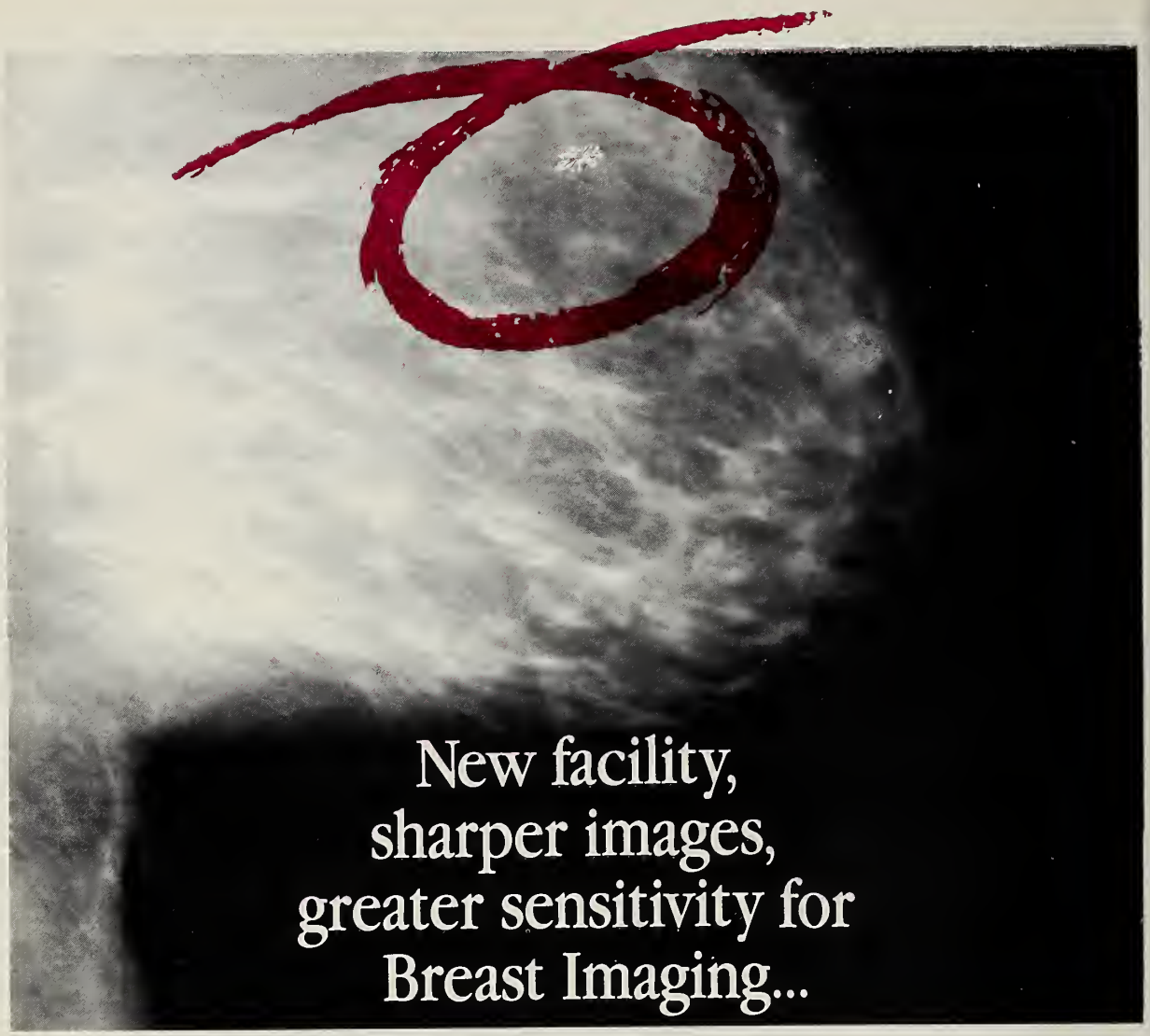

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CONTENTS

411 PRESIDENT'S PAGE
"Tails"

413 OPEN HEART SURGERY FOR CONGENITAL HEART DEFECTS: OVERVIEW AND REVIEW OF THE EARLY EXPERIENCE AT THE MEDICAL CENTER OF DELAWARE
Kathleen W. McNicholas, M.D.
Jorge Serra, M.D.
N. Peter Karmilowicz, M.D.
Paschal M. Spagna, M.D.
Gerald M. Lemole, M.D.

421 RECURRENT PERIANAL STREPTOCOCCAL CELLULITIS
Ricardo Castro, M.D.
Jaime Rivera, M.D.

425 VENOUS RECONSTRUCTION IN VENOUS INSUFFICIENCY SYNDROME
Syde A. Taheri, M.D.

431 SPECIAL REPORT: HOUSE CONCURRENT RESOLUTION NO. 121

433 MEDICAL ETHICS
Statement on Physician Advertising
Ethical Guidelines for Professional Advertising

439 IN BLACK AND WHITE

441 DEATHS
F.B. Lane Haines, M.D.

443 EDITORIALS
Primary Care: New Patterns of Training
David Platt, M.D.
Therapy of Peptic Ulcer Disease: The Doctor's Dilemma
Harris R. Clearfield, M.D.

447 WHERE THEY STAND: BUSH AND DUKAKIS ON HEALTH AND RELATED TOPICS

459 BOOK REVIEWS

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CONTENTS

551 PRESIDENT'S PAGE
A Ronald McDonald House for Delaware

559 JOHN A. BROWN, BOTANIC PHYSICIAN
Everett D. Bryan, M.D.

569 ACCEPTANCE OF MATERNAL ALPHA-FETOPROTEIN SCREENING IN WILMINGTON HOSPITAL'S OBSTETRICAL CLINIC
Karen Byrne-Essif, M.S.
John Naber, M.S.
Garrett H.C. Colmorgen, M.D.

573 LUNG CANCER IN RUBBER MANUFACTURING WORKERS: TWO CASE REPORTS
Rosemary K. Sokas, M.D.
Thorne Sparkman, Jr., M.D.
Walter J. Levinsky, M.D.

579 MEDICAL ETHICS
Allowing the Dying to Die
H. Robert Silverstein, M.D.

585 EDITORIALS
Posttransfusion Hepatitis
Jane Straughn, M.D.
Amplification
Bernadine Z. Paulshock, M.D.
Delaware Psychiatry Circa 1988
Cathryn Clary, M.D.
Edward Schweizer, M.D.
Long Term Care: What Does It Cost?
Edward R. Sobel, D.O.
Should Pharmaceutical Companies Provide CME?
Bernadine Z. Paulshock, M.D.

597 DELEGATES' REPORT: 1988 ANNUAL MEETING OF THE AMA HOUSE OF DELEGATES
Daniel A. Alvarez, M.D.

603 DEATHS
Elton Resnick, M.D.
Ervin L. Stambaugh, M.D.

605 LETTERS TO THE EDITOR

609 IN BLACK AND WHITE

611 BOOK REVIEWS

617 IN BRIEF

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C O N T E N T S

627 PRESIDENT'S PAGE
Report of the President

633 ADVANCES IN THE DRUG MANAGEMENT OF RHEUMATOID ARTHRITIS
John H. Klippel, M.D.
Jeffery Shiroky, M.D.

641 GROWING PAINS
Robert A. Doughty, M.D., Ph.D.

647 THE WOLF INSIDE
John Stone, M.D.

651 LYME DISEASE: A HISTORICAL PERSPECTIVE
James H. Newman, M.D.

659 AEROBIC EXERCISE IN THE MANAGEMENT OF RHEUMATIC DISEASES
Russell J. Labowitz, M.D.
Jayne Challman, M.S.
Scott Palmeri, R.P.T.

665 FROM COMPUTER MODELING TO FDA APPROVAL: RESEARCH STRATEGY FOR THE DISCOVERY OF NEW ANTI-ARTHRITIC DRUGS
Neil R. Ackerman, Ph.D.

669 VIEW BOX
Common Arthritic Manifestations
Richard Wallace, M.D.
Paul McCready, M.D.

675 MEDICAL ETHICS

679 EDITORIALS
Spotlight on the Guest Editor
Introduction
James H. Newman, M.D.
Omega-3 Fatty Acids in Rheumatoid Arthritis
Joel M. Kremer, M.D.
A History of the Arthritis Foundation, Delaware Chapter
Christopher R. Donoho, Jr. M.D.
Digitorum Nodi: Little Hard Knobs
Bernadine Z. Paulshock, M.D.

685 LETTER TO THE EDITOR

687 DEATHS

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SPECIAL ISSUE
PUBLIC HEALTH SERVICES IN DELAWARE
Lyman J. Olsen, M.D., M.P.H., Guest Editor

C O N T E N T S

697 PRESIDENT'S PAGE
Salve Atque Vale

701 THE EDITORS FAREWELL
Bernadine Z. Paulshock, M.D.

702 THE NEW EDITOR'S INTRODUCTION
E. Wayne Martz, M.D.

705 THE DIVISION OF PUBLIC HEALTH
Lyman J. Olsen, M.D., M.P.H.

707 PUBLIC HEALTH SERVICES IN DELAWARE

CHANGES IN HEALTH LAW

721 New Laws and Their Importance to Disease Prevention
Paul R. Silverman, Dr. P.H.
David E. Wolfe, P.A., R.N., M.P.H.

726 New Birth and Death Certificates
Michael L. Richards

727 DELAWARE STATEWIDE ADOLESCENT HEALTH STUDY - 1987
Lucille P. Siegel, M.P.H.

735 SMOKING IN DELAWARE: ECONOMIC COSTS AND DEATHS ATTRIBUTABLE TO CIGARETTE SMOKING IN THE STATE, 1985
Fred N. Breukelman
Paul S. Zeitz, D.O.
Thomas E. Novotny, M.D.

741 EDITORIALS
From the Obvious to the Optional
The Importance of Public Health Measures
Public Health for Public Good
Spotlight on the Guest Editor

747 MEDICAL ETHICS

749 COMMITTEES OF THE MEDICAL SOCIETY OF DELAWARE, 1988

755 INDEX, Delaware Medical Journal, Volume 60, 1988
Part I, Subject: Part II Authors

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President's Page

ARE WE A SELF-SERVING GROUP?

Our professional organizations and societies are often attacked and characterized as self-serving groups with an economic preoccupation. This criticism can be heard among some physicians as well.

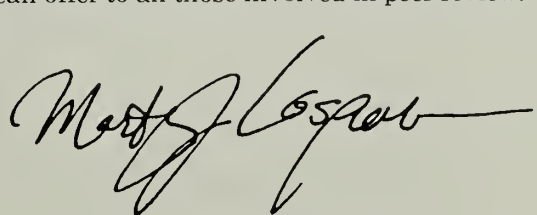
The recent position on AIDS of the AMA's Council on Ethical and Judicial Affairs, which states, "When an epidemic prevails, a physician must continue his labors without regard to the risk to his own health," is neither self-serving nor reactionary, but compassionate and responsive. Although this is a view not shared by all physicians, it is one that challenges all physicians to the highest ethical standards of our profession. It is in fact an expansion of ethical commitment to our patients. I have been greatly surprised by the lack of national media coverage and the absence of political comment regarding this AMA position, given the subject matter and its implications. Is it because this position does not conform to the media's preconception of physicians and American medicine?

The Medical Society of Delaware has responded to the malady and tragedy of AIDS in Delaware by forming an independent Blue Ribbon AIDS Commission chaired by Judge Robert C. O'Hara. Physician members account for only a small minority of the membership. This commission is composed of members from all involved sectors of the Delaware community.

We are castigated as a profession for not properly and adequately monitoring and policing fellow members of our profession. Simultaneously, however, forces are at work to impede the peer review process. Contrary to popular wisdom, it is not possible to have it both ways. The courts have determined that physician activities constitute trade and commerce. Physicians serving on peer review committees are therefore at risk because of possible antitrust litigation for restraint of trade and competition. We are also increasingly at malpractice risk if we do not adequately peer review a problem colleague--as in a very recent landmark malpractice judgment in New Jersey.

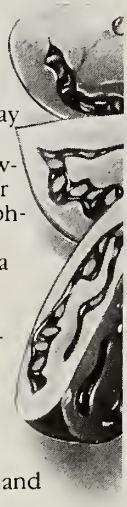
The peer review dilemma could be resolved by the passage of state legislation that would grant protection to peer review by members of the Medical Society of Delaware and the medical institutions of this state. It would be necessary to bring such peer review activities under the Board of Medical Practice. In this way the "State Action Exemption" would apply and there would be immunity from antitrust liability.

In the future, the Society will be looking into legislation that would provide every protection the law can offer to all those involved in peer review.



Martin J. Cosgrove, M.D.

A defense against cancer can be cooked up in your kitchen.



There is evidence that diet and cancer are related. Some foods may promote cancer, while others may protect you from it.

Foods related to lowering the risk of cancer of the larynx and esophagus all have high amounts of carotene, a form of Vitamin A which is in cantaloupes, peaches, broccoli, spinach, all dark green leafy vegetables, sweet potatoes, carrots, pumpkin, winter squash, and tomatoes, citrus fruits and brussels sprouts.

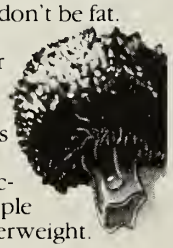
Foods that may help reduce the risk of gastrointestinal and respiratory tract cancer are cabbage, broccoli, brussels sprouts, kohlrabi, cauliflower.

Fruits, vegetables and whole-grain cereals such as oatmeal, bran and wheat may help lower the risk of colorectal cancer.

Foods high in fats, salt- or nitrite-cured foods such as ham, and fish and types of sausages smoked by traditional methods should be eaten in moderation.

Be moderate in consumption of alcohol also.

A good rule of thumb is cut down on fat and don't be fat. Weight reduction may lower cancer risk. Our 12-year study of nearly a million Americans uncovered high cancer risks particularly among people 40% or more overweight.



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Pregnancy: Pregnancy Category B. Teratogenicity studies have been performed in mice, rats, and rabbits at doses up to 50 times the human dose and have revealed no evidence of harm to the fetus due to sucralfate. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when sucralfate is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS
Adverse reactions to sucralfate in clinical trials were minor and only rarely led to discontinuation of the drug. In studies involving over 2,500 patients, adverse effects were reported in 121 (4.7%). Constipation was the most frequent complaint (2.2%). Other adverse effects, reported in no more than one of every 350 patients, were diarrhea, nausea, gastric discomfort, indigestion, dry mouth, rash, pruritus, back pain, dizziness, sleepiness, and vertigo.

DOSAGE AND ADMINISTRATION
The recommended adult oral dosage for duodenal ulcer is 1 gm four times a day on an empty stomach.

Antacids may be prescribed as needed for relief of pain but should not be taken within one-half hour before or after sucralfate.

While healing with sucralfate may occur during the first week or two, treatment should be continued for 4 to 8 weeks unless healing has been demonstrated by x-ray or endoscopic examination.

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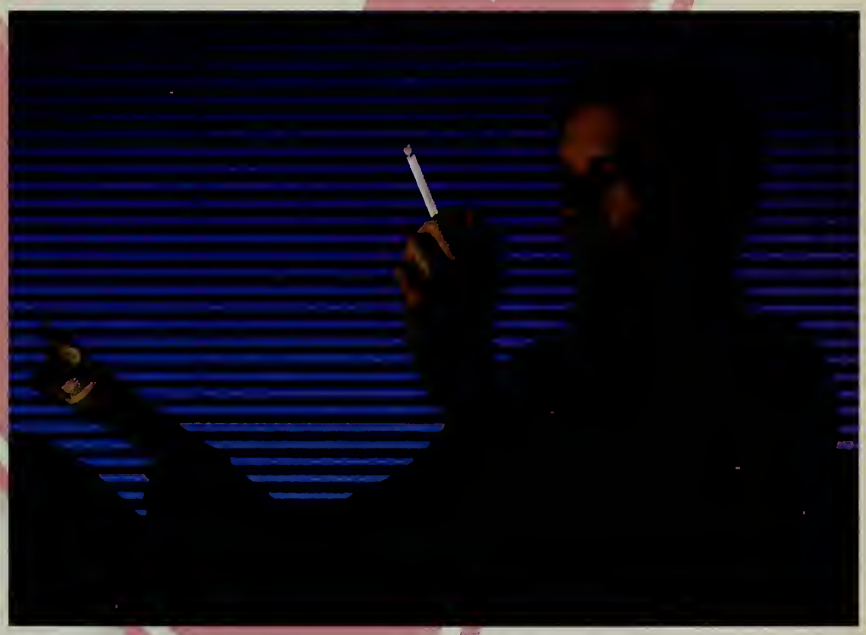

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8.13 SUBSTITUTION OF SURGEON WITHOUT PATIENT'S KNOWLEDGE

To have another physician operate on one's patient without the patient's knowledge and consent is a deceit. The patient is entitled to choose his own physician and he should be permitted to acquiesce in or refuse to accept the substitution.

The surgeon's obligation to the patient requires him to perform the surgical operation: (1) within the scope of authority granted by the consent to the operation; (2) in accordance with the terms of the contractual relationship; (3) with complete disclosure of all facts relevant to the need and the performance of the operation; and (4) to utilize his best skill in performing the operation.

It should be noted that it is the operating surgeon to whom the patient grants consent to perform the operation. The patient is entitled to the services of the particular surgeon with whom he or she contracts. The surgeon, in accepting the patient is obligated to utilize his personal talents in the performance of the operation to the extent required by the agreement creating the physician-patient relationship. He cannot properly delegate to another the duties which he is required to perform.

Under the normal and customary arrangement with private patients, and with reference to the usual form of consent to operation, the surgeon is obligated to perform the operation, and may use the services of assisting residents or other assisting surgeons to the extent that the operation reasonably requires the employment of such assistance. If a resident or other physician is to perform the operation under the guidance of the surgeon, it is necessary to make a full disclosure of this fact to the patient, and this should be evidenced by an appropriate statement contained in the consent.

If the surgeon employed merely assists the resident or other physician in performing the operation, it is the resident or other physician who becomes the operating surgeon. If the patient is not informed as to the identity of the operating surgeon, the situation is "ghost surgery."

An operating surgeon is construed to be a performing surgeon. As such, his duties and responsibilities go beyond mere direction, supervision, guidance, or minor participation.

The physician is not employed merely to supervise the operation. He is employed to perform the operation. He can properly utilize the services of an assistant to assist in the performance of the operation, but he is not performing the operation where his active participation consists merely of guidance or standby responsibilities in the case of an emergency. (I, II, IV, V)

*These citations refer to the *Principles of Medical Ethics* which may be found in the rear of the 1987-88 *Pictorial Roster* of the Medical Society of Delaware.

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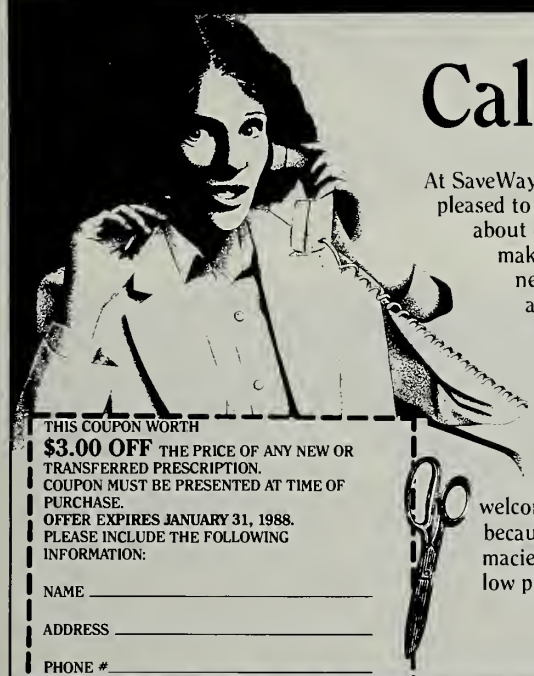

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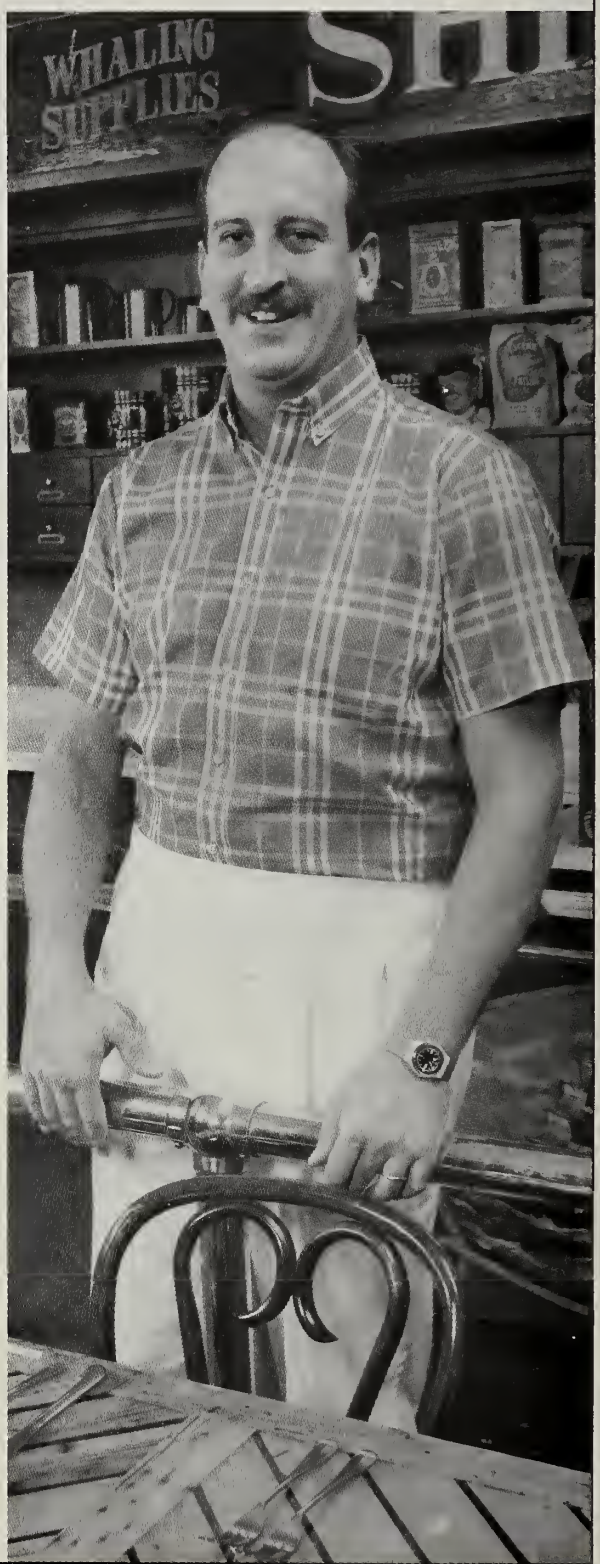

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JANUARY 1988

CURRENT MANAGEMENT OF SPONTANEOUS PNEUMOTHORAX

Festus B. Dada, M.D.
Allen L. Davies, M.D.

INTRODUCTION

Spontaneous pneumothorax occurs predominantly in young adults. It represents the single most frequent cause of admission to the thoracic surgical service in young patients. Rupture of subpleural blebs, usually in the apical region, is the most common etiology.[1,2] Despite this understanding, there continues to be controversy as to the best management of patients with spontaneous pneumothorax. We present 43 cases of recurrent or persistent disease managed by axillary thoractomy, pleural stripping, and wedge lung resection.

SUBJECTS AND METHODS

From 1980-1985, the records of 43 consecutive patients operated on by the senior author were reviewed. Patients with lung malignancy or chronic lung disease were excluded. Patients with single episodes of pneumothorax, managed by tube thoracostomy, were also excluded. The patients ranged in age from 19 to 75 years (mean 34.2 years). There were 24 men and 19 women. Only three had associated diseases, two with lupus erythematosus and scleroderma, and a third patient with Stage 1 carcinoma of the cervix. Dyspnea was the most common symptom present in 84.1%. Chest pain was present in 40%; 15% were asymptomatic. The indications for surgery are listed in Table 1. The patient who was operated on prophylactically was a marine biologist in whom recurrent pneumothorax while scuba diving could be catastrophic.

SURGICAL TECHNIQUE

General endotracheal anesthesia is routine; however, care must be taken to assure that tension pneumothorax does not occur during induction of anesthesia, especially if the chest tube has been removed or has not been inserted in asymptomatic patients with recurrent episodes. We suggest that a sterile hemostat be placed in the tube tract to assure that it stays open until the pleura itself has been opened and the leaking bleb dealt with. The patient is placed with the ipsilateral chest up and the arm positioned on a padded Mayo stand. A transverse incision 8-10 cm long is made beneath the axillary hairline from the lateral border of the pectoralis major to the anterior border of the lattisimus dorsi. The incision is carried to the third intercostal space with electrocautery and the intercostal muscles are divided without entering the pleural cavity, as this maneuver facilitates the subsequent pleural stripping. A small chest retractor is inserted between the ribs and the apical pleural is stripped with the hand. A dry gause mounted on a long sponge forceps allows stripping of remote areas away from the apex.

Since almost all of the patients have asthenic body habitus, about 80-90% of the parietal pleura is stripped. Stripping of the hilar area is performed with extreme caution, as troublesome bleeding may ensue. The floppy pleura is excised with scissors and the unstripped areas are abraded with dry gauze sponges. If there are apical blebs, a TA 30 or TA 55 stapler of appropriate size is used to perform a wedge excision. Two #28 chest tubes are inserted and the wound is closed in layers. The

Dr. Dada, a former chief resident in the Department of Surgery at The Medical Center of Delaware, is currently in private practice in California.
Dr. Davies is chief, Section of Cardiothoracic Surgery at The Medical Center of Delaware, and clinical professor of Surgery, Thomas Jefferson University Hospital, in Philadelphia.

TABLE 1

INDICATIONS FOR AXILLARY THORACOTOMY AND PLEURAL STRIPPING

INDICATIONS	NO. OF CASES	PERCENTAGE
Recurrent Episode	25	58
Persistent Airleak	14	33
Bilateral Disease	3	7
Prophylaxis	1	2

skin is always closed with continuous subcuticular sutures. The chest tubes can ususally be removed on the second or third postoperative day, as air leak, if any, stops promptly. It is noteworthy that the blood loss for this procedure is usually less than 100cc, no intensive care is required, rib resection is unnecessary, and the average operating room time is about 50 minutes.

RESULTS

There has been no necessity for reoperation in any of these patients, either in the immediate postoperative period for hemorrhage, or remotely for recurrence of pneumothorax. The average postoperative hospital stay of 4.9 days (range 3-12 days) is considerably less than for patients with median sternotomy, or anterior or posterolateral thoractomy. There was no mortality in this group. Morbidity has been minimal at 6.9% (3/43). One patient developed a minor wound infection which improved with warm compresses and antibiotics. One patient had a loculated small pneumothorax which had completely resolved by the time of discharge, and one patient had significant segmental atelectasis which required intensive pulmonary toilet. The patients with associated diseases fared just as well as the others, and even the older patients (7/43 were over 50 years old) conformed to the total picture of low morbidity and early hospital discharge.

All of the patients have been followed from four to 48 months (mean 3.3 months) by us, and by their family physicians. There has been no recurrent pneumothorax on the operated side. Two patients have since been operated on for contralateral involvement.

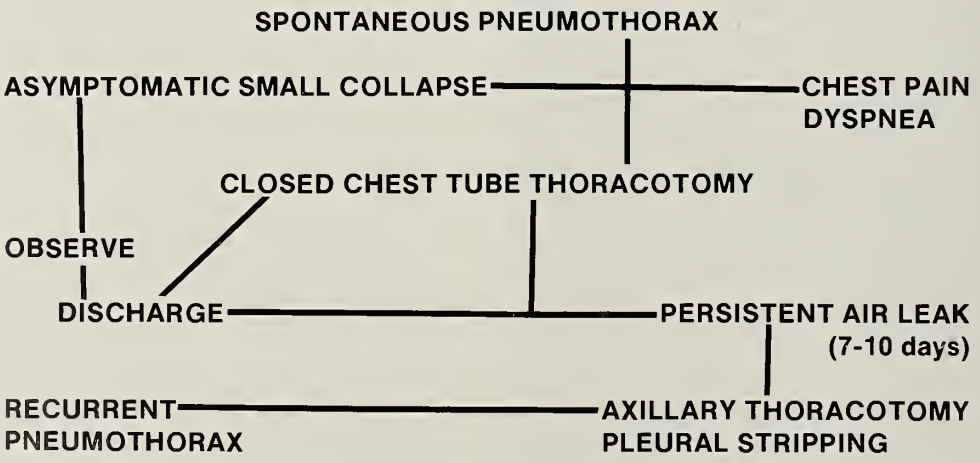
DISCUSSION

Spontaneous pneumothorax afflicts relatively young adults with congenital apical blebs. When older patients are affected, there is usually an underlying obstructive pulmonary disease. Since the report by Gaensler in 1956, controversy continues as to whether parietal pleurectomy is too radical a procedure for this disease.[3] Clagett maintains that the ensuing adhesion of the lung to the endothoracic fasia makes subsequent thoractomy very hazardous.[4]

There are also proponents of modalities viewed as less invasive for the management of patients with spontaneous pneumothorax. Some groups believe that patients with an initial episode could

FIGURE I

ALGORITHM FOR MANAGEMENT OF PATIENTS WITH SPONTANEOUS OR RECURRENT PNEUMOTHORAX



be managed by restriction of activity and observation. The advantage of this approach is obvious, but since these are young people, their lifestyle would be severely disrupted by such an approach. Secondly, the incidence of recurrence, trapped lung, and infection is high if the lung is not rapidly reexpanded. Needle aspiration of the pleural cavity has been suggested by others. We and others[1,2] have had little success with this method; therefore, we almost never employ the technique. Instillation of various sclerosing agents have also been utilized by various groups. Askew[5] and Clagett[1] maintain that since the diaphragmatic and mediastinal pleural scarify the most with sclerosants, the resulting adhesions are usually inadequate to prevent recurrent pneumothorax, since in about 70% of these patients the underlying pathology is in the apical region. While the use of the Heimlich valve device has received some enthusiastic support,[1,4,6,7] others have had less success with it. It is the opinion of Gubbel that this device provides inadequate evacuation of air from the pleural cavity.[8]

The approach that we have routinely used in symptomatic patients with significant lung collapse with the initial occurrences is closed chest tube thoracostomy (Fig. 1). A #28 French chest tube is placed in the fourth intercostal space in the anterior axillary line and connected to 20 cm suction until air leak stops and the tube is removed. This method is effective, predictable, and allows most patients to be discharged after a short hospital stay. The other methods previously described lack equal effectiveness.

Transaxillary thoracotomy is a simple, safe procedure to perform. Roos[9] has used this approach since the mid-1960s for management of thoracic outlet syndrome, and others[10,11] have reported its use in patients with spontaneous pneumothorax and for open lung biopsy of pulmonary lesions.

Most authors use a transverse incision;[10-12] others have advocated a vertical axillary approach, although it is not well received.

We believe that any approach must meet certain criteria to be acceptable. It must cure the disease and result in no mortality. The morbidity must be minimal, it should be cosmetically acceptable, and in these days of cost-consciousness in health care, it must be cost effective. Our experience when compared to with other series[1,2,5,10,11,14] indicates that this method meets all of the above criteria (Table 2). We have been particularly impresssed that the patients accept the cosmetic appearance of their scar.

CONCLUSION

The use of axillary thoractomy, parietal pleurectomy, and wedge resection of pulmonary blebs for the management of spontaneous pneumothorax in 43 patients has been discussed. We are convinced that the axillary approach is safe, simple,

TABLE 2

COMPARATIVE SERIES OF THORACOTOMY FOR PLEURAL STRIPPING

Series	Thoracotomy Approach	# of pts.	Average Hospital Stay (days)	Mortality %	Major* Morbidity %	Minor** Morbidity %	Percent Recurrence
Brooks 1973	Standard	33	N/A	0	12	1	N/A
Saha et al 1975	Standard	27	12	0	3.7	22	0
Askew 1976	Standard	100	11.2	0	7	6	1
Becker 1976	Axillary	10	—	—	—	—	—
Deslauriers et al 1980	Axillary	362	6	0.27	0.82	1.4	0.55
Present Series	Axillary	43	4.9	0	0	6.9	0

* Postoperative or intraoperative complications requiring further surgical management

** Nonoperatively managed postoperative complications

and effective, and it should be utilized in selective patients with recurrent or persistent spontaneous pneumothorax.

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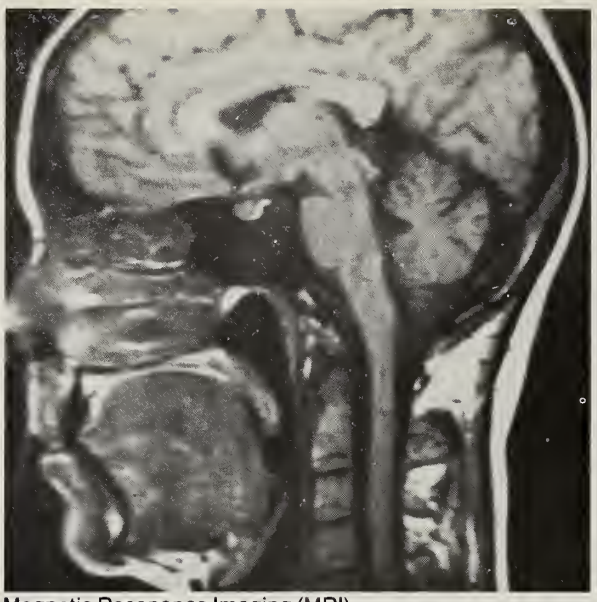

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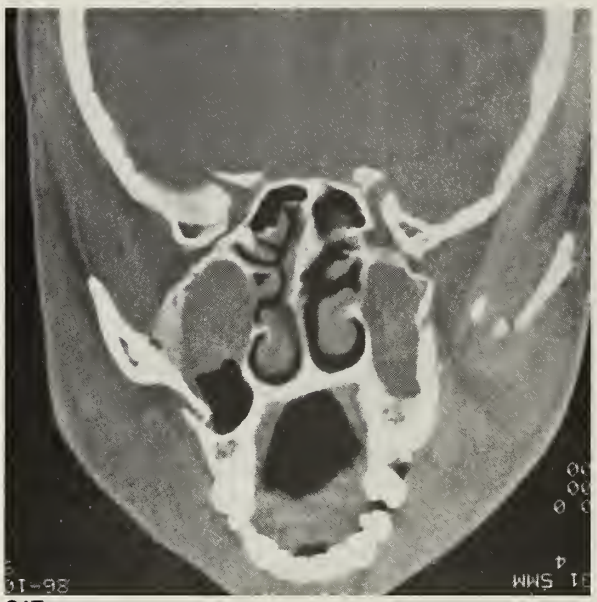

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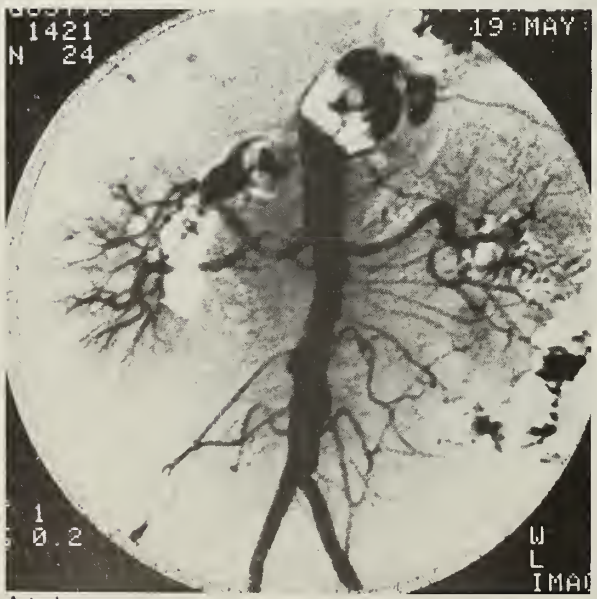

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Medical Classics

MEMOIRE SUR LA FERMENTATION APPELEE LACTIQUE

David Platt, M.D.

"I think I should tell in a few words how I came to be engaged in research on fermentation.

"My research has been dominated by the idea that the structure of substances. . .plays an important part in the most intrinsic laws of the organization of living beings, and enters into their most obscure physiologic properties. . .I hope I can. . . interrelate the phenomena of fermentation and the property of molecular dyssemetry peculiar to organic substances.

"I propose to establish. . .that just as there is an alcoholic ferment, the yeast of beer, to be found wherever sugar breaks down into alcohol and carbonic acid, so there is a specific ferment, a lactic yeast, always present when sugar turns into lactic acid, and that if any nitrogenous plastic material is able to convert sugar into that acid, this is because it provides a favorable food for the development of that ferment.

"The purity of a ferment, its homogeneity, its free development without hindrance, upon nourishment accurately adapted to its individual nature. . .this is one of the essential conditions for successful fermentation.

Dr. Platt is a family practitioner in Wilmington. He is a senior attending physician at The Medical Center of Delaware, and an instructor in Family Practice at Jefferson Medical College.

"The conclusions to be drawn from the foregoing facts will be apparent to everyone. The breakdown of sugar into alcohol and carbonic acid is a correlative action of a vital phenomenon, an organization of cells, in which the sugar takes a direct part by supplying a portion of the constituents of the substance of those cells.

"Throughout this Mémoire I have reasoned on the hypothesis that the new ferment possesses an organized structure, that it is living, and that its chemical action on sugar is correlative with its development and its organization."[1]

* * *

At the time Pasteur presented this Mémoire to the Société des Sciences de l'Articulture et des Arts de Lille, he was only 34 years old. His work immediately revolutionized the industries concerned with the production of vinegar, wine, and beer. Later, he developed the preservation of beverages and foods by the process we honor as pasteurization, and the control of silkworm disease by hygienic procedures.

Pasteur envisioned the development and use of antibiotics to treat disease, but was not himself interested in this. His goal was either to develop a vaccine specific for each infection, or to prevent the infection by public health measures.

"I never think of a remedy for a disease, but instead search for a means of preventing it," he said. He forecast the modern era by his interest in studies focused not on warfare against microbes, but on development of host resistance techniques that would increase physiologic resistance to disease and result in peaceful coexistence with pathologic agents. Among many other factors he included both physical fatigue and mental stress.

Pasteur produced rabies immunity in dogs by injecting them with infected spinal cord rendered noninfectious by heating. He explained that the living rabies produced a substance which retained its immunityconferring properties even after death of the virus itself.

In 1882, when phylloxera, a plant louse, was destroying the vineyards of Europe, Pasteur said, "The insect. . .must have some contagious disease of its own and it should not be impossible to isolate the causative microorganism of this disease. One would next produce artificial foci of infection in countries affected by the phylloxera." He succeeded in doing this, and rescued the vineyards.

In 1887, there was an economically disastrous plague of wild rabbits in Australia. Said Pasteur, "So far one has employed mineral poisons to control this plague. . .Is it not preferable to use, in order to destroy living beings, a poison also endowed with life and capable of multiplying at a great speed?. . .I should like to see the agent of death carried into the burrows by communicating to rabbits a disease that might become epidemic." And this he did, with resultant control of the rabbit population.

Louis Pasteur was not only a great creative scientist, but a thoughtful humanitarian. On the occasion of his seventieth birthday, he reflected on the recent wars in Europe. "You bring me the deepest joy that can be felt by a man whose invincible belief is that science and peace will triumph over ignorance and war, that nations will unite, not to destroy, but to build, and that the future will belong to those who will have done most for suffering humanity."

Were Louis Pasteur alive today, he would be in the forefront of the fight against nuclear arms.

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Editorials

NATIONAL CHOLESTEROL EDUCATIONAL PROGRAM

On November 15, 1985, the National Heart and Lung and Blood Institute (NHLBI) initiated a National Cholesterol Educational Program (NCEP) in response to compelling evidence that elevated blood cholesterol poses a clear risk for development of atherosclerotic vascular disease, the leading cause of death in the United States. In justifying this broad approach to cholesterol control, the NHLBI cited long recognized epidemiologic evidence implicating the importance of elevated blood cholesterol in the development of coronary heart disease,[1] and acknowledged the results of the Coronary Primary Prevention Trial (CPPT)[2] as evidence that treating elevated cholesterol reduces morbidity and mortality resulting from the hypercholesterolemic state. Since the CPPT, other trials have been reported demonstrating favorable influence of colestipol/niacin,[3] and gemfibrozil[4] on ischemic heart disease.

On October 6, 1987, after approximately two years of planning involving the concerted efforts of over 20 participating organizations, the Physician's Cholesterol Education Program (PCEP) was launched in Washington, D.C., as the primary professional component of the NCEP. The American Heart Association (AHA) was delegated the responsibility for adminstering this phase of the NCEP.

There are three major goals of the PCEP. The first is to reemphasize the prognostic significance of elevated lipid levels. The second goal is to familiarize physicians with the recently acquired data which demonstrates that lowering lipid levels does in fact reduce morbidity and mortality due to ischemic heart disease. Finally, programs will be outlined which make it possible to have a favorable impact in lipid levels through dietary and, when indicated, drug therapy.

In initiating the PCEP the Delaware Affiliate of the American Heart Association will do several things. All primary care physicians in the state will be mailed a *Physician's Cholesterol Education Handbook* which contains recommendations for detection, classification, and treatment of high blood cholesterol. The Affiliate will sponsor a series of continuing medical education presentations throughout the state in order to further enable physicians to solidify their skills in treating hyperlipidemias. In conjunction with the local news media, recommendations to reduce dietary cholesterol and fat will be reemphasized and people will be encouraged to know their own cholesterol level.

The NCEP emphasizes the importance of diet as the first and most important form of treatment for hyperlipidemia. The Delaware Affiliate of the American Heart Association will serve as a clearing house for information about professional dietary counseling to assist physicians in providing this service to patients as needed.

The Physician's Cholesterol Education Program provides the medical community with effective means of favorably influencing the health of this state's population. People have never been more interested in taking part in their own medical care. The National Cholesterol Education Program represents a chance for physicians to demonstrate their commitment to practice scientifically sound preventive medicine.

Michael E. Stillabower, M.D.
Chairman of the Board
American Heart Association of Delaware

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INDUSTRIAL MEDICINE AND COMMUNITY DOCTORS

The purpose of this editorial is to produce better communications between occupational doctors and physicians in the private sector in a way that promotes better understanding of each other's problems, utilizes the advantages and strengths of each specialty, assures confidentiality for the patient and the doctor, and expands the knowledge base of patient care for both, so that better patient care results, the patient/employee's rights are preserved, and the private sector and industrial medicine gain effectiveness by mutual cooperation.

Managing disability is a large part of industrial medicine and produces most of the interaction with the employee's doctor. The company physician is a bridge between medicine and management. The company doctor understands medical aspects (most of us having come from private practice), but also realizes the validity of business' concerns with disability.

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For example, if a healthy 45 year old man who does considerable manual labor in his regular job has an outpatient inguinal herniorrhaphy, his supervisor needs to know how long he will need to have fellow workers cover the job or to hire a replacement. On return to work, the supervisor wants information whether or not the employee can do the full job or only light duty, work a full day or start off part time. The occupational physician can provide information obtained from the employee or his supervisor as to what the job requires physically: standing most of a shift, lifting up to 50 pounds frequently, repetitive bending, stooping, or working in awkward positions. He also can tell the surgeon that the employee with all the above job requirements can perform useful work sitting at a console monitoring gauges or other necessary desk work. If the surgeon agrees that his patient can do such light duty, the employee returns on this status until he is ready to resume his full duties, a plan which cuts disability time.

As another example, a secretary has a desk job with comparatively little physical activity. If she fractures her lateral malleolus skiing and subsequently is casted and on crutches, her orthopod may believe she is capable of returning to work. The company physician may delay her return, however, because of the knowledge that she works on the second floor, it is a long way even from the handicapped parking area, and her bathroom is far down the hall.

Pregnancy has always been a major concern for industry. Since it has become a "disability" by government decree and litigation regarding pregnancy so widespread, it is an extremely sensitive area for both obstetricians and industrial physicians. If a pregnant worker is moved from her job to prevent possible injury to the newborn, the worker may charge sexual discrimination. If she remains and the baby has any defect, she may sue for possible job-related cause. Obstetricians need to know exposure histories and to work with the occupational doctor to prevent their patient's use of or exposure to embryotoxic or tetragenic material. Many factors such as a history of previous miscarriages, previous premature delivery, and first pregnancy, especially in the older woman, contribute to the already emotionally-charged issue of pregnancy disability. No rigid rules can be used, as each case is different. The disability days for a premipara may be much more than for the same woman when she is para 2, gravida 3 with otherwise similar conditions. Cooperation and communication between the obstetrician and the industrial physician is paramount for the best care of the pregnant patient/employee.

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To view disability from industry's perspective, consider your reaction if your nurse or secretary has a severe accident or illness, or becomes pregnant. Similar questions have to be answered. For your office to be run effectively, you need to have a replacement, train him or her, and pay two people for one job as long as she is off. If and when your employee can return, even part time, she may be able to tell the replacement where things are, what to do, and something about your patients. The same applies to industry.

Finally, a most important and delicate issue is telling the patient or employee what either the private doctor or the industrial doctor has said. This can be the source of much patient anger and physician anguish. Tact and discretion are necessary, and avoiding the trap of giving one's interpretation of what another has said is essential.

Industrial physicians do realize how busy the private sector is. We appreciate your willingness and cooperation to keep us informed, with employee consent for the benefit of our mutual patients, and we look forward to continued enhancement of this special relationship in the future.

William D. Shellenberger, M.D.

THE DEATH OF BENJAMIN RUSH

In 1812, when the nineteenth century was still new, *The New England Journal of Medicine* published its first issue. Lest purists write to correct us, it was then called *The New England Journal of Medicine and Surgery and the Collateral Branches of Science.* I own a bound volume of most of the issues of the first two volumes, given to me by Henrietta Moore, for a long time this Journal's chief editorial assistant.

The pages are slightly foxed but in general of such excellent condition that I am not sure if the volume is a replica or an original. If it is indeed original, it is part of the continuing testimony to the great staying power of paper from earlier centuries when it was mainly made of rags. (Ours is now made of wood pulp, which yields paper has such a high acid content that the pages of books only 30 years old break--yes, I said break, not tear--when they are turned, for they are that brittle.)

In the fourth issue of Vol. II, under the rubric "Biographical Notice," the passing of Dr. Benjamin Rush at the age of 68 is described:

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After visiting his patients as usual, on Wednesday the 14th of April, he was attacked in the evening, with a violent chill, which was relieved by some brandy and water. In the night he awoke with a very severe pain in the side, attended with great difficulty of breathing. He sent for a bleeder, and ordered him to take eight or ten ounces of blood from his arm. After losing blood he was relieved and slept. A medical friend was requested to visit him, the next morning, and finding him weak and exhausted, he adminstered wine whey, which was evidently very beneficial. His pulse, however, became gradually weaker, and his symptoms soon assumed the prevailing typhus type. Stimulating remedies were administered in as great an extent as the stomach would bear, and external irritation was kept up, but without effect; at about 5 p.m. on Monday,

19th April, he expired. He was perfectly rational, and expected with the greatest composure his approaching dissolution. Some of his last moments were spent in fervent prayer.

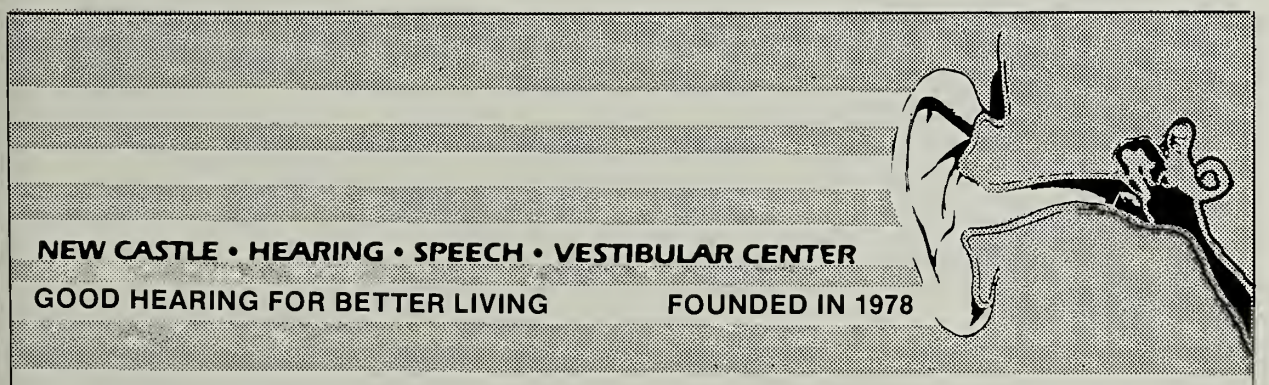
It sounds to me that Rush may have died of pneumonia and that today he might not have succumbed. Certainly, he would have been hospitalized, and quite likely effectively treated within the allowable DRG for acute bacterial pneumonia.

The anonymous author of the note stated that Rush's death "produced the same impression in Philadelphia as a public calamity." While complimenting Rush on his eloquence as a speaker and excellence as a writer, the note concludes with a statement which comes perilously close to speaking ill of the dead:

> He is thought to have improved the practice of medicine in this country in many essential things; though the warmth of his feelings led him to pursue, perhaps with too much ardour, a favorite mode of practice as well as a speculative opinion.

Is this indicative that then as now *The New England Journal* editors did not flinch from telling truth as they saw it, or an early example of an acerb bit of Boston-Philadelphia medical rivalry?

Bernadine Z. Paulshock, M.D.



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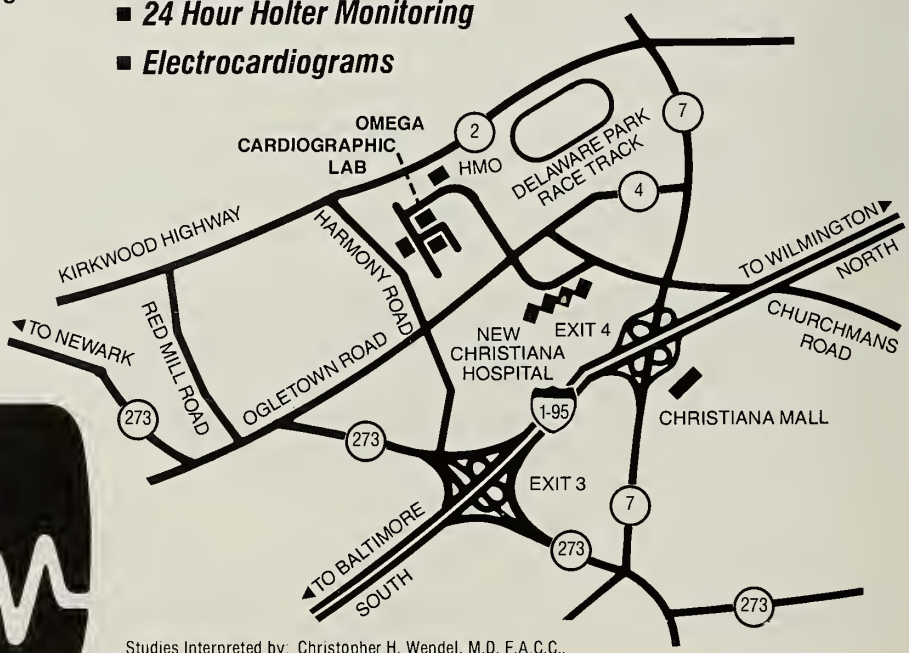

Studies Interpreted by: Christopher H. Wendel, M.D. F.A.C.C.,
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3:40 to 4:00	Unstable angina - Jan R. Weber, M.D.
4:00 to 4:30	Case presentations - Howard Noveck, M.D.
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PROCEEDINGS OF THE HOUSE OF DELEGATES, 1987 PART I

The 198th Annual Meeting of the House of Delegates of the Medical Society of Delaware was called to order at the Delaware Academy of Medicine Building, Wilmington, Delaware, on Friday, November 20, 1987, at 1:30 p.m. with Peter R. Coggins, M.D., President, presiding.

A quorum was declared.

A motion was made, seconded, and approved to adopt the minutes of the 1986 session.

Dr. Coggins then turned the meeting over to Henri F. Wendel, M.D., who acted as Speaker of the House for the reports of the Reference Committees and other Society business.

REPORTS OF THE OFFICERS

REPORT OF THE PRESIDENT

This year, the upcoming annual meeting marks my fifteenth year as an officer and trustee of the Medical Society of Delaware. When Bill Vandervort asked me in 1972 to come on the Board as the Treasurer of the Society, I was stunned and pleasantly surprised, for I had heretofore not been an integral part of county or state organized medicine. I well remember that in those days the entire budget for the Society was some $60,000, we did not have the problems of alphabet soup health care delivery systems, there was no malpractice crisis, we did not have the ethical quandaries that we have today, and we were not faced with the increasing bureaucratization of physicians caught between governmental and private bodies competing for the health dollar. In short, the only common denominator was the care and profound interest that all of us shared in the curing of disease in our fellow man and making life a bit more pleasant for the medically needy.

My long tenure as a journeyman under the many fine presidents that this Society has had the good fortune to elect has served me well in operating in a "broken-field runner position," so to speak, with the complex problems that affect all of us, each in a different way. Nevertheless, in two instances I misread the tenor of some members of this Society and minor problems developed that could have been avoided.

From a financial standpoint, I'm happy to report that thanks to the advice and intense lobbying efforts on the part of my brother, Dr. Eugene Coggins, the Medical Society of Delaware's entire stock portfolio was sold out seven days in advance of the stock market crash on Black Monday, October 19th, and thus, we came through the entire episode unscathed.

On the whole, the Society has made significant strides this year in a broad range of problems such as an investigation in depth of the malpractice problem, the development of a code of ethics, the development of programs to educate our members on the specific problems of the medically aging, the development of a local charitable service program, and the initial investigation and development of a possible alternative medical malpractice insurance system. First and foremost has been the in-depth investigation of the malpractice problem by the Blue Ribbon Panel chaired by Dr. Ben Corballis with county chairmen Drs. Martin Gibbs, James P. Marvel, Jr., and James B. McClements. The members of the panel put in long hours over many months in an effort to develop a series of recommendations, all of which have been approved by the Board of Trustees. These included such substantive moves as the naming of committees to deal with various issues such as improvement of the physician's image, improvement of the medical liability climate (specifically, strengthening of the medical expert section of the current statute), liaison with the AMA in an effort to make Delaware one of the demonstration states for possible alternative systems for resolving professional liability claims, and the development of expanded roles for the medical liability committee with subcommittees including an insurance industry evaluation committee, risk management subcommittee, and subcommittee on tort legislation.

Contact was made with AMA headquarters and Dr. James Todd, who was sent a copy of the Blue Ribbon Panel report. It was Dr. Todd's feeling that Delaware was not a satisfactory environment in which to test a new approach to tort law because of its size. The Board of Trustees plans, however, to introduce in the state legislature in January of 1988 several amendments to the insurance code which will include specific changes to sections in the current expert witness law that are presently extremely onerous.

Concurrently, we have met with Insurance Commissioner David Levinson with regards to the development of an insurance pool in the event that our current insurer decides against medical malpractice coverage of our membership in the future. The development of a risk retention pool is being explored and Commissioner Levinson has given us his wholehearted assurance that every effort will be made by his Department to assist the Society in developing an alternative insurance system that can be utilized in the future in case of an emergency. It should be noted that the legal and administrative expenses for this effort will be in excess of $100,000. However, it will offer an alternative system in case of emergency and will rate physicians' insurance premiums based on the Delaware experience and not on a 50% national experience, 50% Delaware experience as is now the case. The assistance and interest of the Commissioner and his deputy assistant, Kathy Mulholland, are indeed appreciated.

Through the active interest and intense efforts of Dr. Robert Frelick, the Committee on Ethics has developed a set of principles and specific ethical applications in everyday problems. A questionnaire was sent out to the entire membership and from this was developed a consensus approach to many of the nitty-gritty problems that we face in everyday delivery of health care. With respects to the medical aspects of aging, the Committee on Aging, chaired by Dr. Robert Altschuler, has done an exemplary job that led to the development of an annual program in May devoted to medical education and medical care for various problems in aging as well as combined sponsorship with the Medical Center of Delaware of a Geriatric Medical Symposium. When one considers that over a third of our population in the 1990s will be in this age group, the activities of this committee are obviously extremely important.

Our foray into the delivery of charitable medical services has met with fruition through the able assistance of Reverend Lynwood Swanson with development of a volunteer program in conjunction with the Claymont Community Center. This program will be directed towards the providing of primary medical care services in underserved neighborhoods in the Claymont area, where there is a large population of single-parent families and elderly. It is hoped that this approach will be a model for centers in other areas of need in the state.

In the area of sexually transmitted diseases, we were successful through the efforts of Dr. Alfonso P. Ciarlo in helping to obtain for the Department of Health the original budget request, which had been slated to be cut some 53%. This will be of immense help in the treatment of routine STDs as well as in infection control. Considerable funds have also been appropriated for AIDS education and detection. With regards to AIDS, the Society was unsuccessful in a proposal submitted to Senator Herman Holloway for mandatory AIDS testing of health care personnel and patients admitted to state-supported institutions. This bill was modeled after acceptable legislation in other states but met with mixed support and opposition. It is my personal opinion that this type of legislation, with appropriate safeguards for strict confidentiality, will become a national standard in the near future due to the increasing penetration of HTLV-III virus in our population.

In conclusion, I feel that we have accomplished most of what was proposed in my acceptance address one year ago. While there are still many developmental aspects to the programs that are in place, I feel that our Society overall is in excellent shape as far as addressing the problems of the delivery of current medical care.

However, we do have one glaring problem that continues to plague our membership, and that is internal polarization. There are persistent attacks on the traditional delivery of medical care from economic sectors that attribute to us a myriad of problems. Combined with this are unjustified malpractice suits (48% of total instituted suits) which further threaten medical care delivery. We also have a competitive influence from hospitals in an effort to carve out more of the medical market share for themselves, further increasing the polarization among physicians, whom they view in many instances as mere purveyors of a service. Because

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of this, we must guard against increasing self-centeredness in a profession that is basically egocentric and think more of a collective protectionism that fosters increased socialization. Our basic objective is to deliver medical care in a fashion that is of the highest caliber, and to do this we must remain morally strong and work collectively towards fostering that common goal. If that remains the standard for the Medical Society of Delaware, then, like that old General Motors' adage, "What is good for the Medical Society will be good for our patients and for us."

The success of this Society in no small measure is due to the continued perseverance, diligence, and just plain long hours of hard work expended by our Executive Director, Anne Shane Bader. Throughout our many years of association, she has always been a strong and protective advocate for this Society and its interests. As you know, she plans to move over to the Society's insurance agency in two years, and a search committee has been established. She will be sorely missed.

I also want to thank Beverly Dieffenbach for her immeasurable help and assistance throughout the year. The entire staff of the Society is to be commended for their continued interest and efficiency.

I appreciate the honor of having served this Society under fifteen different presidents. While the challenges have been unending, the rewards of seeing this membership grow and continue in the forefront of new and exciting endeavors to serve the needs of the medically needy have been superb. I thank you for the opportunity. I will continue to be a strong advocate for the continued success of our Society, and remain ready to help in any way in the future. May God bless you all.

Peter R. Coggins, M.D.
President

(The report was filed with a commendation to Dr. Coggins on an excellent effort this past year. The Reference Committee noted that a Blue Ribbon Task Force on AIDS is being impaneled by the Medical Society of Delaware from a cross-section of the Delaware Community.)

REPORT OF THE PRESIDENT-ELECT

I have been privileged to serve as President-Elect of the Medical Society of Delaware during the past year. I had previously functioned on the Board of Trustees as Sussex County President and as Secretary of the Board of Trustees. My term as President-Elect was not preceded by a term as Vice-President.

I have acted for the President on occasions when he was otherwise occupied on Society business. I have represented the President or the Society at a variety of conferences and meetings. These have included the Pennsylvania State Medical Society Leadership Conference, the Mid-Atlantic Leadership Conference, the Installation of the President of the University of Delaware, the Annual Meeting of the Delaware Philippine Medical Society, and various discussions and conferences involving issues such as malpractice and Medical Society-Board of Medical Practice relationships.

My Sussex County locus has not denied my active participation in Board and Society activities. This to a significant degree was due to particularly generous consideration by our President, Dr. Peter Coggins, in both the scheduling of meetings and in personal informative contacts.

I have endeavored during this year to serve the President, Dr. Coggins, and the Society to the best of my ability. I am aware of the challenges facing this Society in the coming year of my Presidency. I pledge my most sincere and best efforts and request your cooperation and help in the resolution of these problems.

Martin J. Cosgrove, M.D.
President-Elect

(The report was filed.)

REPORT OF THE VICE PRESIDENT

During the past year, the Vice President was involved in several projects for the Medical Society of Delaware. A few meetings were attended at the behest of the President of the Medical Society.

One commitment was with the United Way of Delaware, where I was chairman of the Physicians' Section. Numerous meetings were held with representatives of United Way, ICI Stuart Pharmaceuticals Division, and the Du Pont Company, who acted as cosponsors of a unique approach to marketing United Way to all physicians. Three levels of giving were established to qualify physicians for several opportunities to win special medical teaching items and other

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prizes for the winning physicians. The entire project was financed by ICI Stuart Pharmaceuticals and the Du Pont Company.

Many physician donors to United Way are credited to places of employment and not to the Medical Society of Delaware; hence, participation rates by members of the Society have been artificially low in past years. This year a different approach will more truly reflect how involved doctors really are.

Henri F. Wendel, M.D.
Vice President

(The report was filed.)

REPORT OF THE SECRETARY

The Society and its subsidiaries have held 119 meetings during the past year. Eleven meetings were devoted to the transaction of business by the Board of Trustees. All business transacted by the Society has been recorded in the minutes as presented by the Secretary.

During the past year the Society has also sponsored a program for the public on "Health Care Issues for the Elderly," hosted the Southeastern States' Reception at the 1986 Interim Meeting of the AMA, and been a Silver Sponsor for the 1987 McDonald's Ladies' Professional Golf Championship.

The Society has been a co-sponsor for the following programs in the past year: Rheumatology Update 1987 -March 3, 1987, with the Delaware Chapter Arthritis Foundation; Medical Aspects of Sports - February 28, 1987, with the University of Delaware; the Physician-Clergy Breakfast - April 9, 1987, with the Department of Pastoral Care, Medical Center of Delaware; A Guide to Services for Older Delawareans - April 21, 1987, with the Department of Medicine, Medical Center of Delaware; Eastern Shore Medical Symposium - June 21-26, 1987, with Jefferson Medical College and the University of Delaware; and Delaware Continuing Medical Education for Physicians 1986-87, with Jefferson Medical College and The Medical Center of Delaware.

A comparison of the Society's membership in 1986 and 1987 follows:

	1987 Membership*		
	Dues-paying Members**	Dues-exempt Members	Total
Kent	77	16	93
New Castle	620	124	744
Sussex	115	20	135
	812	160	972

*Figures do not include 16 pending applications.
**Does not include 18 new members inducted late in 1987 who will be billed for 1988.

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	1986 Membership Dues-paying Members**	Dues-exempt Members	Total
Kent	88	16	104
New Castle	664	128	792
Sussex	124	19	143
	876	163	1,039

Alfonso P. Ciarlo, M.D.
Secretary

(The report was filed with approval of the recommendation that there be in-depth study to determine the number of practicing physicians in Delaware who are not members of the Medical Society of Delaware.)

REPORT OF THE TREASURER

The current fiscal year of the Medical Society of Delaware will close with a sizeable surplus. The Treasurer and Board of Trustees have continued the long-established tradition of fiscal conservation. The proposed budget for the upcoming year is also anticipated to end with surplus.

About 40% of the revenue is derived from the membership dues. Some of the other sources of income are: funds received from the PHICO Insurance Company for risk management, interest accrued from revolving funds in short custody of the Society, and a host of other revenue-generating activities conducted by the staff of the Medical Society.

The Society's membership dues have been kept unchanged during the past 11 years and are now the lowest in the nation.

MSDIS has reimbursed the Medical Society of Delaware for services rendered by its staff.

One major additional source of revenue this year, and probably for the foreseeable future, has been the dividends paid by MSDIS.

It was a good year for the Society's stock portfolio. With the approval of the Budget Committee and the Board of Trustees, the stocks were sold prior to the major crash in the market. Our portfolio has grown from about $60,000 of four years ago to a current total of $104,000.

In summary, the sources of revenue are well defined and realistic at this time. The allocated funds for expenditure are necessary and conservative. Until such a time that the probability of a major imbalance appears on the horizon, I recommend no fundamental change in our fiscal policy.

It has been a pleasure and an honor for me to work with the officers and the trustees of the Medical Society of Delaware in this past year.

Ali Z. Hameli, M.D.
Treasurer

(The report was filed with the followiong attachments.)

MEDICAL SOCIETY OF DELAWARE

TREASURER'S REPORT

OCTOBER 31, 1987

OPENING BALANCE		
01/01/87, Bank of Delaware		$ 38,723.50
RECEIPTS		
1987 Dues	Collected in 1986	13,419.00*
	Collected in 1987	142,695.00
Services		57,370.36
Interest/Dividends		115,807.35
Refunds		100.00
Misc.		38.05
TOTAL RECEIPTS		$316,010.76
Reimbursed		7,798.37
Transfer		69,100.00
DISBURSEMENTS		
Employee Benefits		24,586.38
Salaries		119,362.41
Employer Tax		8,273.97
Office Operation		
Contribution to Academy		10,080.00
Printing, Postage, Stationery, Telephone, Supplies		21,631.38
Xerox/Maintenance Agreements		6,295.36
Kelly Services		864.43
Corporation, Unemployment Taxes		9,640.18
Committees and Contingency		16,591.22
Public Relations		13,345.05
Legal Counsel		6,133.65
Accounting		4,830.00
DMJ Dues-Exempt Subscriptions		1,620.00
Roster		8,000.00
Travel and Contingency		5,061.69
Subscriptions/Periodicals		755.68
Insurance		9,530.00
Risk Management		596.55
Dues/Contributions		4,504.00
Newsletter		3,548.45
Misc.		10.00
TOTAL DISBURSEMENTS		$275,260.40
Reimbursable		4,326.16
Transfer for Interest		136,000.00

RESTRICTED FUNDS

RECEIPTS		
1987 AMA Dues		
Collected in 1986 - 23,084.00*		
Collected in 1987		233,940.50
1987 Kent Dues		
Collected in 1986 - 2,080.00*		
Collected in 1987		4,080.00
1987 Sussex Dues		
Collected in 1986 - 450.00*		
Collected in 1987		710.00
Delaware Medical Journal		
Collected in 1986 - 710.00*		
Collected in 1987		7,550.00
Education Fund		
Collected in 1986 - 355.00*		
Collected in 1987		22,605.60
Medical Benevolence Fund		
Collected in 1986 - 71.00*		
Collected in 1987		27,697.85
Auxiliary		
Collected in 1986 - 2,065.00*		
Collected in 1987		3,657.50

MEDICAL SOCIETY OF DELAWARE & SUBSIDIARIES

Consolidating Balance Sheet
December 31, 1986

ASSETS	Medical Society of Delaware Current Fund	Medical Society of Delaware Restricted Funds	Medical Society of Delaware Custody Fund
CURRENT ASSETS			
Cash	$ 70,866	$ 38,307	$ 284,808
Cash (escrow)	***	***	***
Accounts receivable	15	***	***
Investments at cost	59,994	***	***
Investments in and advances to subsidiaries	27,842	17,361	***
Prepayments	***	***	***
	158,717	55,668	284,808
PROPERTY AND EQUIPMENT			
Leasehold improvements	7,556	***	***
Furniture and fixtures	24,265	***	***
	31,821	***	***
Less: Accumulated depreciation	23,229	***	***
	8,592	***	***
	$167,309	$ 55,668	$284,808
LIABILITIES			
CURRENT LIABILITIES			
Dues payable	$ 29,094	$ ***	$ ***
Income taxes payable	4,125	***	***
Payroll taxes payable	973	***	***
Due to affiliate	17,361	***	17,869
Accrued expenses payable	38,167	***	***
	89,720	***	17,869
DEFERRED REVENUES			
Revenues received in advance	38,419	426	***
	128,139	426	17,869
FUND EQUITY			
FUND BALANCE	39,170	55,242	266,939
COMMON STOCK	***	***	***
RETAINED EARNINGS	***	***	***
	39,170	55,242	266,939
	$167,309	$ 55,668	$284,808

Delaware Medical Journal Current Fund	Medical Society Of Delaware Insurance Services, Inc.	Eliminations	Consolidated
$ 9,788	$ 67,487	$ ***	$471,256
***	428	***	428
***	12,975	***	12,990
***	***	***	59,994
***	***	(45,203)	***
***	4,564	***	4,564
9,788	85,454	(45,203)	549,232
***	***	***	7,556
13,587	5,074	***	42,926
13,587	5,074	***	50,482
10,848	4,885	***	38,962
2,739	189	***	11,520
$ 12,527	$ 85,643	$(45,203)	$560,752
$ ***	$ ***	$ ***	$ 29,094
***	15,991	***	20,116
710	288	***	1,971
9,873	***	(45,103)	***
***	498	***	38,665
10,583	16,777	$(45,103)	89,846
***	***	***	38,845
10,583	16,777	$(45,103)	128,691
1,944	***	***	363,295
***	100	(100)	***
***	68,766	***	68,766
1,944	68,866	(100)	432,061
$ 12,527	$ 85,643	$(45,203)	$560,752

Annual Meeting:	
Exhibits	15,225.00
Grants	3,351.00
Activities	3,630.00
Blood Bank	1,675.00
SE Coalition	20,810.20
CME Program	16,590.00
TOTAL RESTRICTED FUNDS	$361,522.65
DISBURSEMENTS	
AMA Dues	257,644.00
Kent County Dues - 1987	5,650.00
Sussex County Dues - 1986	225.00
1987	650.00
Delaware Medical Journal - 1986	70.00
1987	8,245.00
Education Fund - 1986	30.00
1987	20,849.12
Medical Benevolence Fund - 1986	7.00
1987	27,767.35
Auxiliary - 1987	10,270.00
Annual Meeting - 1986	13,369.45
1987	2,774.00
Blood Bank	1,557.00
CME Program	6,327.66
SE Coalition	20,348.61
Dues Refund	567.00
TOTAL RESTRICTED DISBURSEMENTS	$376.351.19
CLOSING BALANCE	
10/31/87, Bank of Delaware	$ 1,217.53

* $42,234.00 total was collected in 1986 for 1987 dues. This figure is reflected in the opening balance of 01/01/87.

Ali Z. Hameli, M.D.
Treasurer
Medical Society of Delaware
1925 Lovering Avenue
Wilmington, DE 19806

We have examined the consolidated balance sheet of the Medical Society of Delware (a Delaware Corporation) and Subsidiaries as of December 31, 1986, and the related consolidated statements of revenues and expenses, and changes in fund equity for the year then ended. Our examination was made in accordance with generally accepted auditing standards and, accordingly, included such tests of the accounting records and such other auditing procedures as we considered necessary in the circumstances.

In our opinion, based on our examinations, the consolidated financial statements referred to above present fairly the financial position of the Medical Society of Delaware and Subsidiaries as of December 31, 1986, and the results of their operations and the changes in equity for the year then ended, in conformity with generally accepted accounting principles applied on a consistent basis with that of a preceding year.

April 25, 1987 — Haggerty & Haggerty
Wilmington, Delaware — Certified Public Accountants

REPORT OF THE BOARD OF TRUSTEES

The following is a summary of some of the issues considered by the Board that are not discussed elsewhere in this handbook.

The physician biennial registration license fee was increased this past year from $30 to $70. This was done at the request of the Board of Medical Practice, but the Board then learned it is not allowed to keep the money it collects. It goes into the General Fund and helps support other boards. The Board of Trustees adopted a motion that funds collected by the Board of Medical Practice should be retained and budgeted for the Board's activities.

The subject of capital punishment was discussed, bringing forth a great deal of diverse opinion with regards to various attitudes, both pro and con.

The Board was informed that the Division of Public Health is developing regulations for freestanding surgical centers, emergency centers, and birthing centers.

The Society co-sponsored a program with the Delaware Dietetic Association on April 30, 1987, at the Delaware Academy of Medicine Building.

The Board learned that Public Law 99-660 will result in a federal data bank for the Department of Health and

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Human Services, insurance companies, and Boards of Medical Examiners, and that health care entities will be required to report payments as a result of malpractice awards or settlements and disciplinary actions.

The Pharmaceutical Manufacturers' Association asked the Society to join in its effort to oppose the new drug benefit program that is part of the Medicare Catastrophic Plan that will be voted on by the Senate.

Dr. William H. Duncan represents the Board of Trustees on the Board of the West Virginia Medical Institute, Inc., the PRO for Delaware. Through six reports over the past months, he has attempted to keep the Board of Trustees of the Medical Society informed of what is happening to Delaware physicians through the PRO. (These reports are filed in the Society office and are available upon request.)

Anne Shane Bader
Executive Director

(The report was filed with a commendation to Dr. Duncan for his efforts on behalf of Delaware physicians at meetings of the West Virginia Medical Institute and the recommendation that the Board investigate the Medicare Catastrophic Plan and disseminate its findings to the membership.)

REPORT OF THE AMA DELEGATE

The 1987 Annual Meeting Report was published in the August, 1987 issue of the *Delaware Medical Journal.* (The report was filed.)

REPORT OF THE PRESIDENT OF THE KENT COUNTY MEDICAL SOCIETY

The Kent County Medical Society has had three quarterly meetings during the past year.

At the November 19, 1986, meeting the following officers were elected to two-year terms: President--Leroy B. Buckler, M.D.; Vice President--William Alloy Rosenfeld, M.D.; Secretary-Treasurer--Stephen Cooper, M.D. Trustees to the Board of Trustees of the Medical Society of Delaware are Jeffrey L. Chait, M.D., and Robert E. Heckman, M.D.

Nine new members were presented and inducted into the Kent County Medical Society during the year, and there was one transfer from the New Castle County Medical Society into the Kent County Medical Society. Kent County now has 77 dues-paying members and 16 dues-exempt members.

Four problems were referred to the Professional Conduct Committee. Three have been resolved, and the fourth appears as if it will soon be resolved.

Leroy B. Buckler, M.D.
President

(The report was filed.)

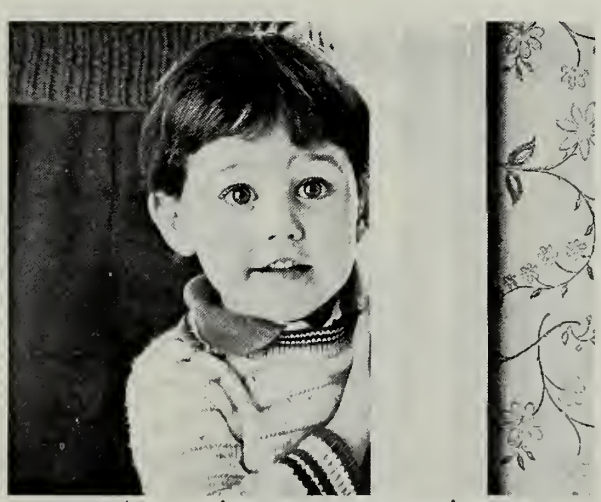
REPORT OF THE PRESIDENT OF THE NEW CASTLE COUNTY MEDICAL SOCIETY

The New Castle County Medical Society held quarterly membership meetings throughout the year. In addition to the quarterly meetings, the Board of Directors and other Standing Committees were also active.

At the Society's Annual Business Meeting, Grafton Reeves, M.D., representing the Health Plan of Delaware, presented a bronze plaque to the Society in recognition and appreciation for the many hours of dedication to the development of the physicians' IPA/HMO. He also presented the Society with a check for reimbursement of meeting expenses related to the development of the Plan.

Ben C. Corballis, M.D., Chairman of the Medical Society of Delaware's Blue Ribbon Malpractice Panel, presented a summary of the Panel's report at the May meeting. The Panel was charged with the task of examining the malpractice crisis in Delaware. He reviewed the results of a malpractice questionnaire which was completed by Society members and discussed the current medical liability statutes in Delaware. Overall, the Panel felt Delaware statutes were excellent; however, they did feel that certain areas, such as "punitive damages" and "joint and several liability," could be fine-tuned.

At the most recent meeting, Dean L. Winslow, M.D., presented an excellent update on the management of AIDS patients. In addition, Paul Silverman, State Epidemiologist, and Joan Schwartz, Infection Control Officer at The Medical Center of Delaware reviewed AIDS statistics for Delaware and outlined precautions for dealing with AIDS patients.



During the course of the year, the Board of Directors held regular monthly meetings to discuss medical issues and the management of the Society. Standing Committees were also busy performing various duties for the Society. The Professional Conduct Committee, chaired by Richard Winkelmayer, M.D., reviewed numerous complaints between patients and physicians. The Peer Review Committee, chaired by Gustave K. Berger, M.D., for part of the year and Richard T. D'Alonzo, M.D., for the remainder, reviewed disputes between physicians and addressed quality of medicine issues. The Community Affairs Committee, chaired by Stephen R. Permut, M.D., and the Legislative Committee, chaired by William H. Duncan, M.D., were also active. Since November of 1986, the Judicial Board, chaired by Janet Kramer, M.D., reviewed and accepted 40 new members.

Joseph F. Kestner, Jr., M.D.
President

(The report was filed.)

REPORT OF THE PRESIDENT OF THE SUSSEX COUNTY MEDICAL SOCIETY

The Sussex County Medical Society had its first meeting of 1987 in January. Mr. W. Davis and Mr. P. Kurtz, two accountants from Washington, D.C., addressed the group concerning the new Federal Income Tax Law.

Claudia Melson was our second speaker and she met with us in April. She is an Archeologist working with the State of Delaware and her talk was titled "Historic Treasure from the DeBraak."

Our next meeting will be on November 5. Mr. Robert Schollkapf, the Director of the New Jersey Marine Mammal Center, will be the speaker. His talk is titled, "Why Are the Dolphins Dying?"

My greatest desire as President of the Sussex County Medical Society has been to bring to our group interesting and informative speakers who appeal to both physicians and physicians' spouses. This is sometimes a difficult task! For 1988, we can look forward to the following possible speakers:

1. A member of the U.S. Americas Cup Sailing Team.
2. An ecologist interested in the Delaware Estuary.
3. A local artist.

Lawrence A. Virgilio, M.D.
President

(The report was filed.)

REPORT OF THE REPRESENTATIVE TO THE DELAWARE ACADEMY OF MEDICINE

The services provided by the Delaware Academy of Medicine continue to grow to meet the needs of its members. During 1986, the Academy's Lewis B. Flinn Library filled 6,762 interlibrary loan requests and performed 479 on-line computer searches. This was an

increase of 23% and 41% respectively, over 1985. For 1987, we are projecting an increase of 10%. The Academy's Circuit-Riding Medical Librarian Program remains active and is currently providing library services on a contractual basis to Kent General Hospital, Milford Memorial Hospital, Riverside Hospital and the HMO of Delaware. The Library also maintains cooperative arrangements with The Medical Center of Delaware Library and various other local and regional library consortiums for the benefit of its members.

As a public service, the Academy operates the Tel-Med Program which provides New Castle County residents with access to tape-recorded messages on a variety of medical and dental topics. This service is also available in Kent County through co-sponsorship with Kent General Hospital. There are currently 275 tapes in the system and we receive an average of 7,900 calls per month.

Our monthly publication of the *Calendar of Medical and Dental Meetings* is distributed statewide to health care professionals. This important publication is the only comprehensive monthly listing of Continuing Medical Education for physicians and dentists. We appreciate the cooperation and support of the hospitals and the medical and dental societies in compiling this information.

For the 1987/88 academic year, the Academy's Student Financial Aid Program provided a total of $45,500 in loans to 25 Delaware residents attending medical and dental school. In addition, the Student Financial Aid Committee distributed $223,000 in scholarships to 49 Delawareans attending Thomas Jefferson Medical College through the DIMER Program. All loans and scholarships were determined by the Committee based on a financial need analysis of each applicant.

The Academy's Auditorium and Lower Level Conference Center continue to be a focal point for numerous meetings. The primary users of the facility are the Medical Society of Delaware, The Medical Center of Delaware, the New Castle County Medical Society, and the Delaware State Dental Society.

On March 6, 1987, the fifty-seventh Annual Banquet was held with 125 members in attendance. The guest speaker was Robert L. Brent, M.D., Chairman of the Department of Pediatrics at Jefferson Medical College. In addition, the Executive Committee held regular meetings during the year to discuss the operation of the building and other issues pertaining to the medical and dental community.

The Delaware Academy of Medicine maintains a close association with the Medical Society of Delaware and appreciates their continued cooperation and support of Academy programs.

Leonard P. Lang, M.D.
Representative

(The report was filed.)

REPORTS OF THE STANDING COMMITTEES BUDGET COMMITTEE

The Budget Committee met on September 16, 1987, and after carefully reviewing the current and proposed budgets of the Society as well as the investment portfolio, recommended the following for the upcoming fiscal year:

1. Efforts to maintain and maximize sources of revenue other than membership dues.
2. The stocks in the portfolio should be sold and the proceeds invested in CDs and securities.
3. No increase in the membership dues should be necessary.
4. A modest increase in the salary line for the staff.

MEDICAL SOCIETY OF DELAWARE

BUDGET - 1988

RECEIPTS		
Dues	$160,650.00	
Services	70,000.00	
Interest	176,911.00	
CME Program	17,000.00	
Delaware Medical Journal, Educ. Fund, Medical Benev.	14,600.00	
TOTAL RECEIPTS		$439,161.00
DISBURSEMENTS		
Office Personnel		
Employee Benefits	$ 30,540.00	
Salaries	152,700.00	
Employer Tax	10,500.00	
Office Corporate, Unemployment Taxes, etc.	8,000.00	
Contribution to Academy	10,080.00	
Printing, Postage, Stationery, Telephone, Supplies, etc.	23,000.00	
Service Contracts/ Xerox	10,000.00	
Audit	5,000.00	
Insurance	10,000.00	
Kelly Services	3,000.00	
Travel and Contingency	7,000.00	
Subscriptions	700.00	
Contribution/Dues	900.00	
Legal Counsel	18,000.00	
Public Relations	18,000.00	
Committees and Contingency	20,000.00	
Continuing Medical Education	10,000.00	
Newsletter	5,000.00	
Delaware Medical Journal, Educ. Fund, Medical Benev.	14,600.00	
Physicians' Health Committee Phone	500.00	
Computers	10,000.00	
TOTAL DISBURSEMENTS		$367,520.00

5. The Budget Committee will review the job specifications and the salary structure for the Executive Director, the Assistant Executive Director, and other staff members.

The current budget will leave a sizeable surplus. The proposed budget for the upcoming fiscal year is also anticipated to end in the black. It will allow for the continuation of all present programs and activities.

The financial status of the Medical Society has remained good and stable in the past. The membership dues have been kept unchanged during the past ten years and now are the lowest in the nation. This has been due to a judicious fiscal restraint by the Board of Trustees and the House of Delegates and sizeable dividends received from the insurance subsidiary of the Society. The committee recommends the continuation of this practice.

Ali Z. Hameli, M.D.
Chairman

(The report was adopted.)

BYLAWS COMMITTEE

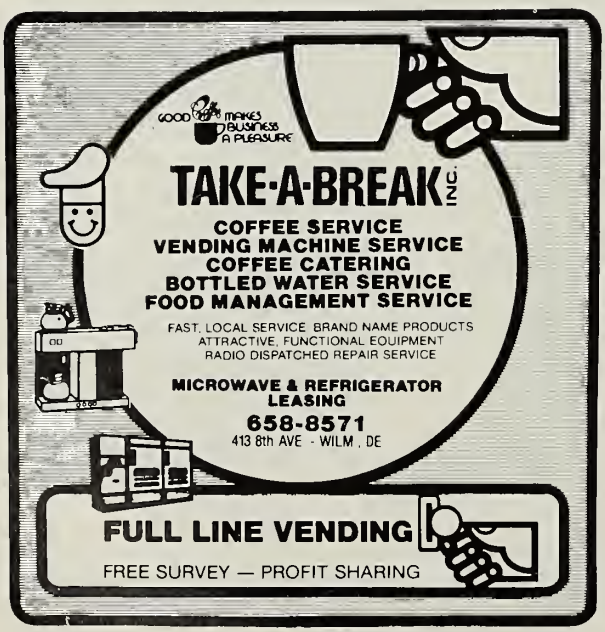
A meeting of the Bylaws Committee was held on September 28, 1987, at the Delaware Academy of Medicine Building in Wilmington. Six of seven members of the committee were present.

The first item discussed was a resolution from the Society's Board of Trustees in support of de-unifying membership with the AMA.

De-unification would require a Bylaws change deleting Section 1 of Article III (Membership) of the Society's Bylaws. This section states:

Membership in the American Medical Association or the American Osteopathic Association is mandatory for all Medical Society of Delaware members.

According to Article XIII, Section 16, of the Society's Bylaws, all proposals for amendments to the Bylaws shall be submitted to the Bylaws Committee for consideration and recommendation.



The following recommendation was unanimously adopted by the committee following discussion of the issue: That the resolution not be adopted and that the Society's Bylaws not be amended at this time.

The next topic discussed was the procedure to be followed when an office becomes vacant due to the death, resignation, removal, or disqualification of any officer. The Bylaws now provide that the President may, with the confirmation of the Board of Trustees, fill the vacancy by appointment. The Bylaws do not limit the powers of the appointee in any manner. Therefore, if the appointee is the President-Elect or Vice President, he or she would have the right of succession without having been elected by the House of Delegates. It was also noted that the Bylaws at present state that the Vice President and not the President-Elect is to succeed the President upon the death, resignation, etc., of the President. The Bylaws Committee recommends that the Bylaws be amended as follows: Strike Section 4 (Vacancies: How Filled) of Article V (Officers) in its entirety and substitute in lieu thereof the following:

Section 4
VACANCIES: HOW FILLED

If the President dies, resigns, or is removed, or becomes disqualified, the President-Elect shall succeed to the office vacated with all the prerogatives and duties pertaining to the office of President and shall, for the unexpired term, also retain all the prerogatives and duties pertaining to the office of President-Elect. If the President-Elect dies, resigns, is removed, or becomes disqualified, the Vice President shall succeed to the office of President-Elect with all the prerogatives and duties pertaining to the vacated office. If the office of Vice President becomes vacant for any reason, it shall remain vacant until the next session of the House of Delegates. Vacancies created by death, resignation, or removal of officers and vacancies in contingencies not herein provided for shall be filled by the President and confirmed by the Board of Trustees for the unexpired portion of the term.

Also suggested was revision of Article V to provide that the Vice President may officiate during the absence of the President and the President-Elect. The Bylaws Committee recommends that Section 7 (Vice President) of Article V (Officers) be amended as follows: Add the words "and may officiate for him during the absence of the President and the President-Elect" after the word "duties" at the end of the first sentence.

JUDICIAL COUNCIL

As chairman of the Judicial Council, I am pleased to report that during the past year no cases have been referred to the Judicial Council for review or decision.

Marvin H. Dorph, M.D.
Chairman

(The report was filed.)

MEDICAL ECONOMICS COMMITTEE

There have been no meetings of the Medical Economics Committee this year.

Consideration of the role of this committee is now underway, since it appears that the functions of this committee have been taken over by other standing committees.

Martin J. Cosgrove, M.D.
Chairman

(The report was adopted.)

MEDICAL LIABILITY INSURANCE COMMITTEE

The Medical Liability Commitee has had an active year. As is normally the case, the committee meets with our insurance carrier to discuss new rate filings and changes in the basic contract.

During this year there have been suggested changes by PHICO which were rejected and changes which were accepted. The committee was not willing to consider a change in the terms relevant to the provision of free "tail coverage." Therefore, these provisions remain the same as they were when the program started.

In early July, the committee met with representatives of PHICO who announced that it would be necessary to file for a overall 30.7% rate increase for the coming year. PHICO presented a substantial amount of statistical information to show the justification for this rate increase. The committee was reluctantly forced to agree that it appeared to be a proper business decision. Therefore, the committee voted to allow PHICO to file these rates with the Insurance Office, but without the committee taking a stand for or against the rates.

At this meeting we once again discussed with PHICO what changes could be made in the program to protect the general premium structure from the negative influence of physicians who have several lawsuits. It was decided that PHICO would explore the possibility of a deductible program and report back to the committee.

On July 23, 1987, the representatives of PHICO once again met with the Liability Insurance Committee. PHICO proposed a deductible program which would enable physicians to choose a deductible level which would suit their practice. The levels were generally $10,000, $20,000, $50,000 and $100,000. Each of these would produce a discount on the premium rate. The discount for the $100,000 deductible would be 30%, thereby almost obviating the increase in premium. However, there was much discussion over whether or not the deductible program would be suitable for most physicians.

It should be stressed that the deductible would be only on awards or settlements. All cost of defense would continue to be borne by PHICO.

PHICO also at that time proposed a change in the rules governing the program which would be a departure from the past. The most important proposal was that of the "consent to settle" agreement. PHICO proposed that under the deductible program they would revoke the right to consent to settlement clause. This caused great discomfort to the committee and considerable discussion ensued. We asked PHICO to reconsider this proposal.

It was also stated that those physicians who qualified for free "tail coverage" would, if they chose a deductible program, also have a deductible in their tail coverage. This deductible would be limited to the first two cases under the tail coverage and then it would resume full coverage.

Questions were asked as to whether or not there was any other method of having a deductible program and it was explained that there was such a thing as a "shared deductible" program. The committee asked PHICO to study that and come back to the committee with a subsequent proposal.

The committee met with PHICO once again on August 20, 1987. At this time PHICO proposed a shared deductible program. Once again the levels were as described and the savings on the premiums were commensurate with the levels of deduction. There was about a 10% drop in the savings at each deductible level from the non-shared deductible.

Most importantly, PHICO changed its position on the "consent to settle" clause. Under this shared deductible program, the physician would retain the right to consent to settle. However, if PHICO recommended settlement at a certain dollar figure and the physician refused permission, any subsequent settlement or award above that level would become the responsibility of the physician. While the committee was not terribly happy with this change, it understood that it was a necessary business decision on the part of PHICO.

When the committee was satisfied that it had achieved the best possible program change at the time, it voted to approve PHICO's filing with the Insurance Commissioner's office of this new shared deductible program.

It was agreed by PHICO that once they prepared the necessary brochures and information on this program, two meetings would be held with the insureds. One would be held in Wilmington and one would be held in Dover so that each physician would have an opportunity to hear the details of the program first-hand and to make an informed decision on whether or not to choose to take part in the shared deductible program. It is to be clearly understood that the shared deductible program is absolutely voluntary and that the ordinary full coverage program is still in effect.

The committee felt strongly that one of the strong points of the shared deductible program would be that it would offer protection to the Society and to a physician who was in danger of either not having his insurance renewed or who had come to Delaware and applied for coverage under our program. At the present time, if a physician requests help from the Society because of imminent cancellation or difficulty obtaining insurance under our program, the only options open to a subcommittee are to recommend that PHICO either insure the physician or allow PHICO to carry out its decision not to insure. Under the shared deductible program, the subcommittee would also be able to recommend to PHICO

that the physician be offered a shared deductible contract. This would protect the Society program from the effect of multiple suits and yet would enable the physician to obtain coverage.

During the past year four physicians appealed to the Society for help because their insurance was either in jeopardy or, in the case of new applicants, PHICO had declined to offer coverage. In each instance a subcommitee was impaneled, the case considered, and a conclusion reached. In one instance the physician was covered after taking a period of retraining, and in the other three cases PHICO agreed with the subcommittee and issued standard policies to the physicians.

I congratulate the members of the committee, and especially those who served on the subcommittees, for their diligent effort on behalf of the Society during the past year.

Ben C. Corballis, M.D.
Chairman

(The report was filed with a commendation to Dr. Corballis for an excellent job in a very difficult area.)

MEDICAL REVIEW COMMITTEE

There were no requests for review before the Medical Review Committee in 1987. Many of the matters formerly handled by the Medical Review Committee, such as fee disputes, requests from insurance companies regarding charges, and requests from patients for review of fees, have been handled by the Professional Conduct Committee of the New Castle County Medical Society. This committee has the same exposure for antitrust action as the Medical Review Committee of the State Society. It is recommended that closer liaison be established between the County Society's Professional Conduct Committee and the State Society's Medical Review Committee for screening of these complaints so they can be referred to the proper committee for review. The committee desires to remain active for review of matters concerning professional fees and to operate within the guidelines established for review of these fees.

Anthony L. Cucuzzella, M.D.
Chairman

(The report was filed.)

PEER REVIEW AND PROFESSIONAL EVALUATION COMMITTEE

I would like to respectfully submit this report of the Peer Review and Professional Evaluation Committee from the last House of Delegates' meeting to the present.

It was a very active year for both Kent and New Castle Counties. Apparently Sussex County had no problems; nothing was reported. Kent County had four complaints, of which three were resolved. One has just been reviewed, and it appears as though it will be resolved.

New Castle County has had monthly meetings to discuss various problems, as noted below.

1. One problem concerned a physician in regards to his practice of physical therapy. After review it was decided that there were problems with his methods of charging and his length of treatment, and the Board of Directors of the New Castle County Medical Society was so informed. After much discussion, the Board decided to form a subcommittee to look into the matter more closely and discuss the subject with the physician. At the present time the Peer Review Committee has not heard that this has been resolved, and therefore this case is still open.

2. The committee also met with a doctor regarding x-rays and ultrasound. An understanding was reached, and the physician will follow the course laid out by the Peer Review Committee. This will be reviewed in six months to a year.

3. In another case, a cardiologist received a somewhat unsettling letter from a wife who was worried about the circumstances of her husband's death. After meeting with the cardiologist and experts in the specialty, it was found that the cardiologist had performed his specialty with maximum care. After discussion with the wife to answer her questions, the problem was resolved.

4. A situation concerning a surgeon and the problems of contractual agreements between IPA-HMOs and family doctors and specialists who are on the list of HMOs was looked into very carfully. This appeared to be a misunderstanding between the specialist and the family doctors involving the contractual agreements of each with the IPA-HMO. The misunderstanding appeared to be ironed out, but we then received a letter from the

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surgeon, and since this was not purely a peer review problem, we referred him to the Board of Directors and to the State Society's Ethics Committee.

5. Another problem involved a cardio-therapeutic establishment, its ethics in regards to solicitation, and the employed physician's required duties concerning the cardiac status of patients and testing. The committee worked out requirements that were acceptable to the facility. This problem shows that the concept of peer review is becoming broader as physicians and non-physician organizations are brought together to perform tasks where total control is not by the physician. These types of businesses will have to be peer reviewed, and it will be the Peer Review Committee's job to set up protocols for looking into these kinds of situations.

There has been much discussion on the legal status of peer review and credentialing committees in case suits arise. Across the country credentialing committees and other review committees are being sued, and this raises questions in our minds. Members of these committees are performing a service in order to ensure that the public receives the best medical care possible. All this places a great responsibility on the members of these committees, and to the best of my knowledge these members take their duties very seriously and do an excellent job. Yet in the litigious-type era in which we now live, members of these committees are being sued. It is therefore this committee's strong recommendation that the House of Delegates ask the president of the Society to form a committee to look into this problem, to get a written legal interpretation of the law, and to determine if the review committees associated with the various HMOs and hospitals and other type organizations all fall under the same laws as do the physicians under the Society's aegis. If they are not wholly and totally free of liability, the organizations that are using these committees should carry adequate liability coverage for the doctors who are performing the services for the organizations and the community. The committee is aware that this may take some time and possibly some change in the law, but it requests that a report be made concerning this at the next meeting of the House of Delegates.

I wish to thank all the members of my committee for the support they have given me this year and in past years. Peer review committees and other credentialing organizations will need more acceptability and understanding in order to realize the good that can be done for the public.

Gustave K. Berger, M.D.
Chairman

(The report was adopted with approval of the recommendation that the Board of Trustees explore avenues to provide adequate protection and/or cite existing protection for the members of peer review committees functioning under the auspices of the Medical Society and of hospitals.)

PROGRAM COMMITTEE

The Program Committee hereby records for the official record the program arranged for the Annual Meeting of the Medical Society of Delaware on November 21, 1987.

9:15 a.m.	THE LEWIS B. FLINN LECTURE: "NEW PHARMACEUTICAL HORIZONS--SERUM CHOLESTEROL REDUCTION" Albert Brest, M.D., James G. Wilson Professor of Medicine, Jefferson Medical College
10:00 a.m.	"CANCER SCREENING--1987" Joseph F. O'Donnell, M.D., Associate Professor of Clinical Medicine, Dartmouth Medical School
10:45 a.m.	INTERMISSION
11:15 a.m.	"CURRENT STATUS OF INTERVENTIONAL CARDIOLOGY" John W. Hirshfield, M.D., Associate Professor of Medicine, University of Pennsylvania School of Medicine
12:00 noon	"ARTIFICIAL VOICE" Louis D. Lowry, M.D., Professor and

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Chairman, Department of Otolaryngology, Jefferson Medical College

12:45 p.m. LUNCHEON - GOLD BALLROOM
"TITANIC EXPLORATION"
Christopher von Alt, M.S., Research Engineer, Woods Hole Oceanographic Institution, Woods Hole, Massachusetts

2:00 p.m. "AIDS: ETHICAL DILEMMAS"
Robert C. Cassidy, Ph.D., Associate Professor of Family Medicine and Director, Medical Ethics Program, University of Medicine and Dentistry of New Jersey - —Robert Wood Johnson Medical School

2:45 p.m. "TREATMENT OF CUTANEOUS T-CELL LYMPHOMA WITH PHOTOPHORESIS"
Brian Jegosothy, M.D., Professor and Chairman, Department of Dermatology, University of Pittsburgh School of Medicine

3:30 p.m. ADJOURNMENT

As an organization accredited by the Accreditation Council for Continuing Medical Education (ACCME) for its continuing medical education program, Jefferson Medical College designates this activity as meeting the criteria for 5 1/2 hours in Category I of the Physician's Recognition Award of the American Medical Association. The program has been reviewed and is acceptable for 5 1/2 Prescribed hours by the American Academy of Family Physicians.

Suggestions for topics for next year's meeting will be welcomed by the incoming President.

Stephen S. Grubbs, M.D.
Chairman

(The report was filed with a commendation to the committee for a very interesting program.)

PUBLIC AND PROFESSIONAL EDUCATION COMMITTEE

At the Annual Meeting of the Medical Society of Delaware in November 1986, a plea was made for hospitals within the state to seek authorization to conduct and certify their own programs of continuing medical education. In response to this plea, applications were received in May and June of 1987 from Kent General Hospital and Beebe Hospital. The applications were reviewed and site visits were carried out. Both hospitals have had experience conducting educational programs under Jefferson's auspices for several years, and it was evident to the site visit team that they knew what they were doing. The team was favorably impressed in both locations, but some changes were recommended. These were written into a revised application which was acted upon at a meeting of the Public and Professional Education Committee on September 29, 1987. The following recommendations were forwarded to the Board of Trustees of the Medical Society of Delaware for action.

1. That Kent General Hospital be granted provisional approval for two years. At the end of that time Kent General will be resurveyed and the question of their accreditation will be reviewed.
2. That Beebe Hospital be granted provisional approval for two years. Concerns regarding adequacy of facilities
(support by administration) should be discussed with Beebe Hospital in the near future and will be scrutinized at the site visit in two years.

The above recommendations were adopted by the Board of Trustees at its October meeting.

The Medical Society of Delaware is authorized by the Accreditation Council for Continuing Medical Education (ACCME) to accredit institutions within Delaware. However, this authority will be terminated November 1987 unless renewed before that time. A request to the ACCME for extension of the deadline has been refused and an application for renewed authorization is in process as of this writing.

E. Wayne Martz, M.D.
Chairman

(The report was filed.)

PUBLIC LAWS COMMITTEE

The Public Law Committee considered and made recommendations to the Board a total of 67 bills before the State Legislature. Subjects ranged, alphabetically as well as sociologically, from AIDS, alcohol and asbestos through sludge and surrogate motherhood. If one looks for common threads running through this legislative tapestry, one finds ten bills involving safety, nine involving insurance and seven which address various aspects of alcoholism.

The committee wishes to thank the staff of the Medical Society of Delaware and especially Mrs. Beverly Dieffenbach for their constant support and for the continuing practice of serving coffee at our late afternoon meetings.

Allston J. Morris, M.D.
Chairman

(The report was filed with commendation to Dr. Morris for his untiring efforts in an area of great concern to all physicians.)

PUBLICATIONS COMMITTEE

Volume 58 (1986) of the *Delaware Medical Journal* contained 41 original papers, 17 letters to the editor, 44 editorials, and 41 book reviews. Thirty papers were written or co-written by Delaware physicians. Six others were written by members of the greater Delaware community on subjects of interest to the medical profession.

The special issues of the *Delaware Medical Journal* are well-received. March heralded the publication of the first issue entirely devoted to ethics. Maurice Liebesman, M.D., served ably as guest editor. Requests are still coming in for copies of the issue, and Dr. Liebesman has agreed to edit Ethics II for September of 1988. The July issue reprinted in full the report of the Medical Society of Delaware Blue Ribbon Malpractice Panel on the malpractice crisis in Delaware. Dr. Corballis, who chaired the Panel, edited the lengthy report. September's issue on Sports Medicine, edited by Dr. Rebecca Jaffe, featured

a four-color photograph of Wilmington's Dr. William Duncan participating in 1987 Philadelphia Phillies Dream Week. Still pending are a cancer issue guest edited by Dr. Robert Frelick, infectious disease, edited by Dr. Dean Winslow, and a pediatrics special issue guest edited by Dr. Michael Spear. Other special issues of the *Journal* will focus on public health, geriatrics, and diabetes.

In 1987, a new advertising policy was instituted and implemented: advertisements appearing in the *Delaware Medical Journal* for services owned by a physician or physicians must include the names of the physician(s).

The 1987 Editorial Board is composed of: Paul Akana, M.D.; Neal Burton Cohn, M.D.; John A. J. Forest, Jr., M.D.; Harold Graff, M.D.; Rebecca Jaffe, M.D.; William N. Kaplan, M.D.; Jerome Kay, M.D.; Amir Mansoory, M.D.; Harold Marks, M.D.; Mir M. Mousavi, M.D.; Jo Ann Rosenfeld, M.D.; Paula Ryals, M.D.; William D. Shellenberger, M.D.; J. Jordan Storlazzi, Jr., M.D.; Joel R. Temple, M.D.; and John Yindra, M.D. The editor wishes to express her thanks to each of them. They have provided editorial support in the form of manuscript review, book reviews, and editorial material. Others who helped by reviewing manuscripts or answering editorial questions include: Stephen R. Brutcher, D.O.; Arthur W. Colbourn, M.D.; Ben C. Corballis, M.D.; Alan J. Fink, M.D.; Robert W. Frelick, M.D.; Barbara Hamming, M.D.; Joseph F. Kestner, Jr., M.D.; Maurice Liebesman, M.D.; Stephen Permut, M.D.; Charles L. Reese, IV, M.D.; David Raskin, M.D.; Brian F. Smale, M.D.; Christopher H. Wendel, M.D.; Henri F. Wendel, M.D; and Ward Keever, of The Medical Center of Delaware; we thank them all.

Members of the Publication Committee are: Alfonso P. Ciarlo, M.D., Martin J. Cosgrove, M.D., Stephen H. Franklin, M.D., William J. Holloway, M.D., Joseph F. Kestner, Jr., M.D., Robert C. Knowles, M.D., P. John Pegg, M.D., William A. Taylor, M.D., and John S. Wills, M.D. Their contributions to the *Journal* are also deeply appreciated.

Stephen S. Grubbs, M.D., Grand Rounds Editor; Richard F. Gordon, M.D., Medical Classics Editor; John S. Wills, M.D.; View Box Editor, and Dennis R. Witmer, M.D., Photographic Editor, continue to provide excellent material for their features. Dr. E. Wayne Martz, after a long tenure as Book Review Editor, has decided it is time for new blood, and we are currently searching for a replacement.

The staff of the Medical Society of Delaware, especially Mrs. Anne Shane Bader and Mrs. Beverly Dieffenbach, offer invaluable support, assistance and encouragement. Mrs. Anne Elise Spruance, close to completing her second year, is an extremely fine editorial assistant.

Members of the Medical Society of Delaware are encouraged to contribute and to encourage their colleagues to contribute to their *Journal* scientific papers, special reports, letters, editorials, and of course, suggestions for the improvement of the *Journal*. Contributions from Medical Society members are especially welcomed. We are also interested in receiving information concerning the personal achievements of Medical Society members.

Bernadine Z. Paulshock, M.D.
Editor, *Delaware Medical Journal*
Chairman

(The report was filed with the Reference Committee's comment that members of the Reference Committee were disappointed that the *Delaware Medical Journal* did not include articles on AIDS and related issues.)

DELAWARE MEDICAL JOURNAL
Statement of Receipts and Disbursements

	01/01/86-10/31/86	01/01/87-10/31/87
Balance in Checking Account	$ 6,208.03	$ 2,959.75
Total Receipts	54,474.65	48,188.03
Total Disbursements	53,600.58	48,882.77

Anne Shane Bader
Business Manager

(The report was filed.)

The remainder of the reports and resolutions considered at the House of Delegates Meeting will be published in the February, 1988 issue of the *Delaware Medical Journal*.

The complete report of the Proceedings of the House of Delegates is on file at the Medical Society office and is available to members.

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President's Page

DOVER OR BUST

I pose a question for the future of the Medical Society of Delaware. Can a state organization continue to adequately represent all its members when located at the extreme northern periphery of the state? Should there not be equal access to society activities and facilities from "below the canal"? Should the Medical Society of Delaware consider a relocation or at least a presence in a more central location of Delaware?

I acknowledge the architectural treasure that is our present Society location in Wilmington. I recognize that a majority of the physicians of our Society are from northern Delaware. So, however, are a majority of the state legislators who travel to the centrally-located State Capital in Dover for legislative business. State medical societies across the country are positioned largely in central locations and in state capitals, rather than in major population centers. A society presence in or near Dover would certainly facilitate interaction with state government.

We must remain a united and vigorous society, a true state society with physician participation from all parts of our state. New Castle County physicians should be aware that a one hour meeting in Wilmington entails a five hour time commitment by a Sussex County physician. Greater travel time to Wilmington from below the canal secondary to increased population density and traffic congestion is anticipated. Effective disenfranchisement and progressive non-involvement of lower Delaware physicians from Medical Society affairs could result.

The matter is one for consideration by our New Castle colleagues. They are the majority of our membership and they are presently favored by convenient accessibility to the Society. Any future change would be decided by their majority membership and would entail sacrifice of their present location advantages.

Would the long range interests of the Medical Society of Delaware be best served by a central physical location?

Martin J. Cosgrove, M.D.

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DELAWARE MEDICAL JOURNAL

VOLUME 60

NUMBER 2

FEBRUARY 1988

OTITIS MEDIA: AN OVERVIEW OF CURRENT TREATMENT

Robert L. Witt, M.D.

Acute otitis media is defined as an inflammation of the mucoperiosteal lining of the tympanium. The clinical findings are redness of the tympanic membrane, fluid in the middle ear space, fever, and leukocytosis. There are essentially three middle ear effusions: serous, mucoid, and purulent. The prevalence of otitis media is particularly important in the six to 36 month age group of children. Sixty-six percent of children with otitis media are less than three years old.

There are certain socioeconomic factors which play a role in otitis media as well. A much greater prevalence of both serous and acute otitis media in lower socioeconomic groups has been noted. Ethnic groups such as American Indians and Eskimos also have a higher prevalence of both acute and chronic forms of this condition. The peak incidence of otitis media is between December and February. The low incidence is between July and September.

Dr. Witt is an otolaryngologist - head and neck surgeon in Wilmington. He is a member of the staff at The Medical Center of Delaware and St. Francis Hospital in Wilmington. Dr. Witt is also an instructor in the Department of Otorhinolaryngology at the University of Pennsylvania School of Medicine in Philadelphia.

Howie describes children who are otitis prone as those who have more than six attacks of otitis media.[1] Children who are otitis prone tend to have an initial infection with Pneumococcus. The onset of the disease in this group is usually less than one year of age.

The older literature suggested that the pathogenesis of otitis media was due to eustachian tube obstruction which predisposed the middle ear to bacterial colonization of fluid. This was known as the ex vacuo theory. The current concept is that bacteria enter the middle ear space through the lumen of the eustachian tube. Ears with persistent negative middle ear pressure are much more susceptible to otitis media.

The clinical stages of otitis media are: prodromal; inflammation; suppuration; and complication or recovery. The prodromal state is significant for retraction of the tympanic membranes. There is poor mobility to pneumotoscopy. There is also a high negative pressure consistent with a type C tympanogram. The lateral process of the malleus is less prominent. There may be muffled hearing and a low frequency hearing loss. Affected children

may pull at their ears.

In the stage of inflammation there exists an initial subgroup of hyperemia in which the child has malaise, increased temperature, injection of vessels around the margin of the tympanic membrane, and dullness of the tympanic membrane. Movement of the tympanic membrane by pneumotoscopy causes pain. Bacteria may be present on tympanocentesis. A second inflammatory subgroup is the stage of exudation in which there is increased pain and fever with nausea and vomiting. The child may be awakened from sleep. The tympanic membrane, particularly the pars flaccida, is red. The pars tensa may be thick, convex, and bulging. The usual landmarks and the light reflex are lost. A conductive hearing loss is present. A third substage of inflammation is suppuration. In this stage, the temperature may go above 40° C. Pain in the ear is throbbing and pulsatile. The tympanic membrane is bulging and tense, and often will rupture with a gush of yellow serosanguinous fluid. The perforation is usually small and does not enlarge, differentiating it from acute necrotizing otitis media or tuberculosis otitis media, or from acute recurrence of a chronically infected ear.

Severe purulent otitis media usually involves the contiguous mucosa of the mastoid. Technically speaking, every otitis media is associated with a concomitant mastoiditis. Mastoiditis usually refers to a breakdown of the septations of the mastoid cavity. It is more accurately known as coalescent mastoiditis. Generally, the presence of profuse discharge from an ear for longer than two weeks after the tympanic membrane ruptures indicates a coalescent mastoiditis. Also, recurrences of pain, copious purulent discharge and low-grade fevers in otitis media also suggests a coalescent mastoiditis.

Complications may be spread from several routes. Thrombophlebitis of the emissary or perforating veins of the temporal bone may result in early meningitis with few prodromal signs. Infection may also spread via preformed pathways such as suture lines or fracture lines. In chronic otitis media with cholesteatoma, the route of spread is usually by contiguity.

Resolution of otitis media occurs with relief of pain, malaise, and nausea by spontaneous or surgical drainage through the tympanic membrane. If the membrane perforates, in the vast majority of children, it usually heals on its own within three to six weeks.

The eustachian tube has a large role in otitis media and recurrent otitis media. The eustachian tube, middle ear, and mastoid are derived from the first pharyngeal pouch. The length in the adult is 31-38 mm. In the newborn it is usually 21-24 mm. The eustachian tube in adults is 15 mm higher in the middle ear than the nasopharynx, making a 30° angle from horizontal. In children, this angle is less than ten degrees. The shorter length and the more horizontal position of the eustachian tube predispose children to increased episodes of otitis media.

Protection, aeration, and drainage of the middle ear space are the functions of the eustachian tube. The normally closed state of the tube serves to keep microflora and secretions of the nasopharynx from entering the middle ear. With swallowing, the eustachian tube opens and closes intermittently. The tensor veli palatini muscle opens the eustachian tube, allowing air to enter the middle ear space to equalize the ambient atmospheric pressure. If the eustachian tube remains closed, middle ear pressure will fall as air in the middle ear will be absorbed by the vascular network of the mucosa. Retraction of the tympanic membrane ensues, and a transudation of fluid in the middle ear from its capillaries results in the frequently seen case of serous otitis media. Swallowing causes the eustachian tube to open. This occurs five times per minute in the awake adult and one time per minute in the sleeping adult, but only one time every five minutes in the sleeping child. This less frequent opening of the eustachian tube must contribute to the increased problems seen in children. Children with cleft palate nearly all have a defect of the eustachian tube function, and nearly all of them also have episodes of acute and serous otitis media.

Numerous studies regarding the microbiology of otitis media have been performed. The most common bacterial pathogen is *S. pneumonia,* and the second is *H. influenza.* Less than 10% of children have grown out *B. catarhalis* and *Staph aureus.* One quarter to one half of fluid from needle tympanocentesis in acutely infected middle ear spaces will be sterile. The reason for this is that viral and anaerobic etiologies are also possible in otitis media. Brook states that in his study, 15% of tympanocentesis revealed anaerobic bacteria.[2]

Neonatal tympanocentesis reveals a high incidence of gram negative bacteria. The majority of studies indicate that 20 to 30% of all neonatal otitis media is a result of gram negative bacteria.[3] Tympanocentesis is the most accurate technique for isolating organisms from the middle ear space. The indications for a tympanocentesis are in patients not responding readily to antibiotics; children who have rapid relapses; all neonates and children who are immunodeficient; and all cases where a complication is present or suspected.

Antibiotics have greatly reduced the number of

intracranial complications, which occurred at a rate of three percent in the pre-antibiotic era. Because of the liberal use of antibiotics, the chances of intracranial complications are reduced to 0.15%. In the patient who is six weeks and older, antibiotic therapy with amoxicillin, ampicillin, Bactrim (Roche), Septra (Burroughs Wellcome), or Ceclor (Lilly) are all reasonable. In the neonate, gram negative coverage must be considered, and therapy with ampicillin or gentamycin is important. Many medical centers admit children less than six weeks old with otitis media.

The Pittsburgh study has shown that decongestants and antihistamines do not affect the rates of recurrence or cases of residual fluid in the middle ear.[4] The agents may, however, help a coexistent rhinitis.

Prophylactic antibiotics are helpful in recurrent otitis media. Perrin used a double-blind crossover study to compare children treated with sulfa antibiotics with a placebo group.[5] He studied 54 children with recurrent otitis media over six months. The mean number of episodes of acute otitis media in the placebo group was 1.05, which was reduced to 0.15 in the sulfa group. This was statistically significant (P greater than 0.001). Asmer's study, however, reveals that Bactrim is not a good choice for antibiotic prophylaxis, being associated with neutropenia.[6] A better choice would be ampicillin, amoxicillin, or Ceclor. Bluestone's study suggested that prophylactic antibiotic therapy should be used for patients with frequent episodes of otitis media without effusion.[4] He states that a good criteria would be three or more episodes in a six month period.

Pressure equalizing tubes are indicated for persistent middle ear fluid remaining for longer than three months. Recurrent otitis media with four to five episodes over a six month to one year period is also a clear-cut indication. If a child receiving prophylactic antibiotics has a breakthrough infection or persistent middle ear fluid with hearing loss or atelectasis of the tympanic membrane, pressure equalizing tubes are indicated. If middle ear fluid is chronic, underlying causes besides eustachian tube dysfunction should be considered. Underlying causes include paranasal sinusitis, upper respiratory tract infection or allergy, submucosus cleft palate, or nasopharangeal tumor.

The medical therapy of choice for serous otitis media is controversial. A trial of antimicrobial agents is reasonable as serous otitis media is not sterile in 50% of cases tested with tympanocentesis. Convincing studies for nasal and oral decongestants, antihistamines, steroids, and immunotherapy are lacking. Teele's study of 2,565 children found that after otitis media, middle ear effusion was present in 40% of children after one month, and in only 10% after three months.[7]

Another area of controversy in serous otitis media is whether chronic middle ear fluid can cause developmental and speech delays. Though numerous studies have been conducted, the final answer is not clear at this time.[8] If a child exhibits speech delay and has fluid that persists for at least two months but certainly for three months, a pressure equalizing tube should be seriously considered. In winter months there is higher incidence of otitis media with associated suggestive speech delay which should also be treated more aggressively.

The chief complication of pressure equalizing tubes is drainage from the tube. The most likely etiologies of this are twofold. Contamination by water in the ear canal from bathing can frequently result in a middle ear infection. Furthermore, upper respiratory tract infections with bacterial contamination which has ascended through the eustachian tube can result in a middle ear infection which drains through the pressure equalizing tube. This is certainly desirable as it prevents high fever and significant pain that middle ear pus causes while pressing on the tympanic membrane. This latter etiology of drainage from a pressure equalizing tube cannot be considered a true complication. Persistent perforations after pressure equalizing tubes have been put in place are seen in less than one percent of cases.

Pressure equalizing tubes remain in the tympanic membrane on an average from four to 12 months. Statistically, 25% of children require more than one set of tubes. Significant reduction in the number of episodes of otitis media as well as significant improvement in hearing level have been achieved with the use of pressure equalizing tubes.

Otitis media continues to be a frequent but not completely understood clinical entity. In this article, current therapies have been reviewed.

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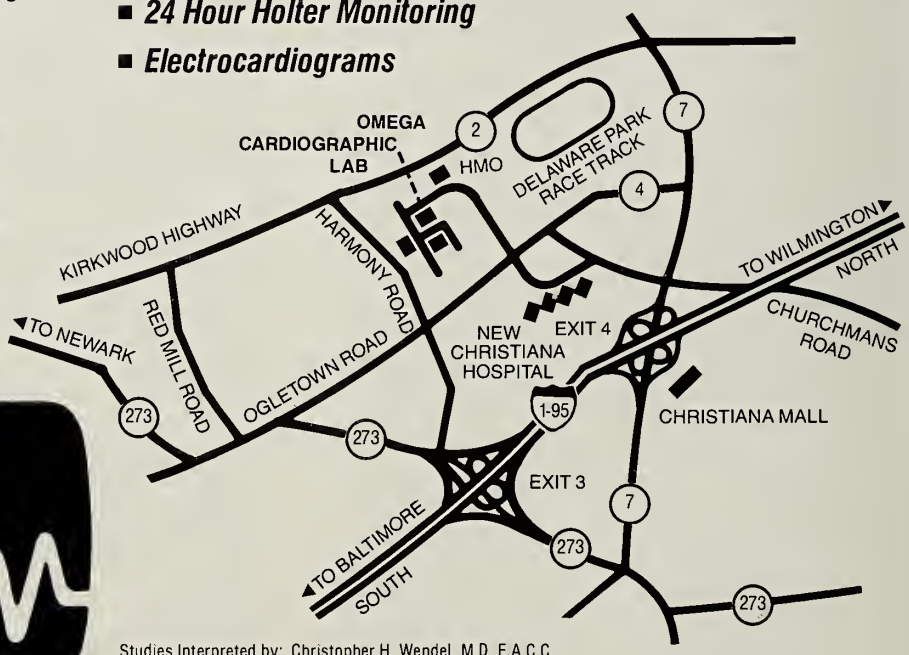

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WOMEN DOCTORS FROM JOHNS HOPKINS

Jo Ann Rosenfeld, M.D.

The Johns Hopkins School of Medicine and the admission of women into the world of medicine were both fairly new in the fall of 1896 when 16 women joined the Johns Hopkins Medical School Class of 1900. Although Elizabeth Blackwell had received her medical degree from Geneva Medical College in 1849, and several Women's Medical Colleges had opened in the intervening 47 years, no male medical school had allowed women to enroll on the same basis as men until Johns Hopkins opened its doors in 1893.

The cause of this unusual acceptance of women was at least partially financial. The Board of Trustees of Johns Hopkins University and Hospital had insufficient funds to finish the building and staffing of a new medical school in the 1890s. An economic depression had reduced donations from usual sources. Mary Garrett, with her friend Martha Thomas, formed the Women's Fund Committee, and raised $500,000 to fund the proposed medical school; a significant portion of the money was donated by Mary Garrett. One stipulation to the donation of the money was:

> That women shall enjoy all the advantages of the Medical School of the Johns Hopkins University on the same terms as men and shall be admitted on the same terms as men to all prizes, dignitaries, or honors that are awarded by competition, examination, or regarded as rewards of merit.

Acceptance of this provision was not easily won. Daniel Coit Gilman, President of the University, asked the Women's Fund Committee if they would substitute "equal terms" for the phrase "same terms" in their proposal, fearing that women would be embarrassed because their mental powers were obviously not as great as those of men. The women ignored the request, the Board finally accepted the terms, and the Johns Hopkins Medical School opened in 1893 as the first medical school to admit women from the date of its inception.

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Sixteen women joined the 25 men to form the Class of 1900. That fall was the first time that there were four full classes in the medical school, 127 students in all. All students were required to have bachelors degrees. Eleven of the women had received theirs from one of the Seven Sister's Colleges, and three from Stanford University. Five had Masters degrees or post graduate science studies. There were several women in the class who later contributed significantly to medicine and to women's health. Two made major contributions to medical education: Florence Sabin, and Clelia Mosher. Dorothy Reed contributed both to clinical medicine and pathology, as well as to public health and health education. At least ten women went into private practice, and one into missionary work in India. Gertrude Stein left medicine to embrace a literary career in Paris.

In medical circles, Florence Sabin is perhaps the best known member of the Class of 1900. She received her B.A. at Smith in 1893, then taught at a private school and at Smith to raise money for her medical school tuition. After medical school and internship at Johns Hopkins, she received a fellowship to study anatomy under Franklin Paine Mall, M.D. She became an assistant in anatomy in 1902, the first woman faculty member of a major medical school. She was also the first woman to

gain a full professorship at Johns Hopkins. She moved to the Rockefeller Institute in 1924, where she stayed until her retirement in 1938. She was the first woman president of the National Association of Anatomists, and the first woman member of the National Academy of Sciences. Dr. Sabin studied the lymphatic system, defining it in more detail than it had been before. She also studied extensively hematological problems associated with tuberculosis, and described the functions of the white blood cells. After retirement, she did not rest, but became the manager of the Denver Department of Health and Charities, working to correct public health problems.

Clelia Mosher was also an educator, and worked hard for the education of women with regard to their own health. Originally refused funds for a college education by her father who thought she was too delicate, she started a thriving business in a greenhouse, raising enough money on her own to attend college at Stanford University when she was 25. She continued there as an assistant in Hygiene, earning her Masters degree with a thesis which disproved the myths concerning the incapacities of women during menstruation. Realizing that her work would not be respected without professional standing, she joined the Hopkins Class of 1900. After graduation, Dr. Mosher took an externship in the Johns Hopkins Hospital dispensary, and then became an assistant to the gynecological surgeon, Dr. Howard Kelly. There, she published *Normal Menstruation and Some Factors Modifying it.* When she was refused further training to become a gynecologist, Dr. Mosher returned to Stanford, where she became an assistant professor in 1910, and full professor in 1928. She continued to crusade to persuade American women to dress and eat sensibly and forgo the dictates of fashion in favor of the good health of their bodies. She published the *Relation of Health to the Women's Movement* and *Women's Physical Freedom* in 1928.

Dorothy Reed literally ran away from the confines of home and caring for her scatterbrained mother to "get into some work that interested me." She graduated from Smith College in 1895, and did a year of postgraduate work at MIT. After her graduation from Johns Hopkins, Dr. Reed's internship was marked with controversy. At that time the top 12 students in each graduating class were offered internships at Johns Hopkins Hospital; especially coveted were the four internal medicine internships under Dr. William Osler. Florence Sabin was third in the class that year, and Dorothy Reed was fifth. When two of the top three men chose other internships, it became obvious that two of the prized internships would go to women. The faculty objected, and offered Dr. Reed gynecology or surgery instead. To solve the impasse Florence Sabin at first offered to take a fellowship in anatomy, but the women decided to take a strong stand and demanded their rights to the internships. Dr. Henry Hurd, Sir William Osler's deputy, objected because one of the two would have to be assigned to the black male ward. Without a strong male intern as protection, he feared that the nurses and students would be threatened by unruly black patients. The women stood by their rights, and both finally were allowed to finish their internships without further incident.

After internship, Dorothy Reed worked as a fellow in Pathology under Dr. William Welch. There she did the research on Hodgkin's disease that linked the double-nucleated Reed-Sternberg cell, diagnostic of lymphoma with her name. She then worked in pediatrics at the New York Foundling Hospital. She married in 1906 and retired temporarily from medicine to have a family. Two of her four children died, one due to obstetric mismanagement. She returned to medicine in public health, crusading for better prenatal care for women, and better pediatric care for their children.

Gertrude Stein was initially the most published student of the class. She received a BA at Radcliffe and had published two articles in her field of Biology while still an undergraduate. However, after a few years, her interest in medicine waned, and she failed several courses. She dropped out before graduation, and immediately left for London and her literary future.

These women faced significant pressure before and during medical school, both to gain admission and recognition as doctors. Dorothy Reed's family for years told friends that she was wintering in the South for her health, unable to bear the scandal of a daughter in medicine. An aunt who lived in Baltimore refused to receive her socially because of her studies. Sir William Osler is reported to have said, "Human beings can be divided into three groups--men, women, and women physicians." During medical school, Dorothy Reed remembered episodes of lecturers delighting in trying to embarrass the women students. One professor offered to publish Clelia Mosher's research as his own, sure that she would accept the compliment that it was good enough to be his work. She refused to allow it, and waited to publish under her own name after graduation.

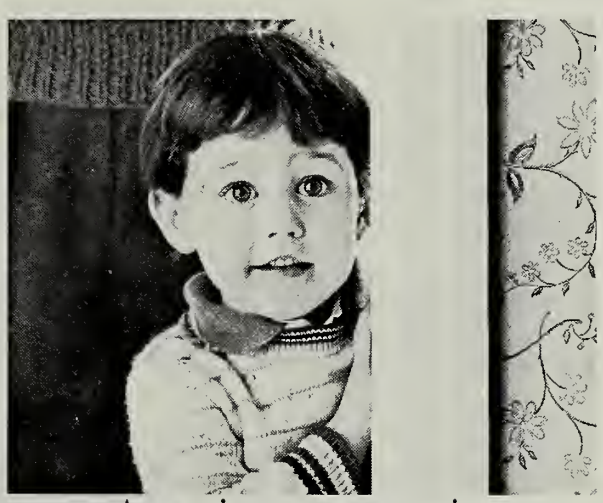
Thirteen of the 16 women students graduated; all contributed significantly to medicine. Johns Hopkins continued to graduate women doctors who were important members of the medical community and their own community.

Dr. Helen Taussig graduated from Johns Hopkins in 1927, and interned in pediatrics there from 1928-1930. She is best known for her collaboration with Dr. Blalock on the blue-baby operations in 1944. She was the first director of the Cardiac Clinic of the Harriet Lane Home, the pediatric clinics of Johns Hopkins, the first woman president of the American Heart Association, and one of the first American doctors to publish articles on the dangers of thalidomide.

Dr. Margaret Handy was a member of Johns Hopkins Class of 1916. After internship at Woman's Hospital in Philadelphia and a residency at Johns Hopkins, she returned to Wilmington in 1919. She created a Children's Ward in the People's Settlement in Wilmington, and worked with Dr. Joseph Wales for the establishment of a Pediatric Clinic at the Delaware Hospital. She was chief of Pediatrics at the Delaware Hospital from 1921 to 1946. Dr. Handy cared for generations of Wilmington children, and taught a generation of doctors her skills and devotion.

All these women contributed greatly to their patients, their students, and their communities in a time when women in medicine were both remarkable and noteworthy.

Parts of this article have been previously published as "The Courage of the Class of 1900," in Medica, *April 1984.*



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Medical Ethics

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5.07 CONFIDENTIALITY: COMPUTERS

The utmost effort and care must be taken to protect the confidentiality of all medical records. This ethical principle applies to computerized medical records as it applies to any other medical records.

The confidentiality of physician-patient communications is desirable to assure free and open disclosure by the patient to the physician of all information needed to establish a proper diagnosis and attain the most desirable clinical outcome possible. Protecting the confidentiality of the personal and medical information in such medical records is also necessary to prevent humiliation, embarrassment, or discomfort of patients. At the same time, patients may have legitimate desires to have medical information concerning their care and treatment forwarded to others.

Both the protection of confidentiality and the appropriate release of information in records is the rightful expectation of the patient. A physician should respect the patient's expectations of confidentiality concerning medical records that involve the patient's care and treatment, but the physician should also respect the patient's authorization to provide information from the medical record to those whom the patient authorizes to inspect all or part of it for legitimate purposes.

Computer technology permits the accumulation, storage, and analysis of an unlimited quantum of medical information. The possibility of access to information is greater with a computerized data system than with information stored in the traditional written form in a physician's office. Accordingly, the guidelines below are offered to assist physicians and computer service organizations in maintaining the confidentiality of information in medical records when that information is stored in computerized data bases. It should be recognized that specific procedures adapted from application of these concepts may vary depending upon the nature of the organization processing the data as well as the appropriate and authorized use of the stored data.

Guidelines on a computerized data base:

(1) Confidential medical information entered into the computerized data base should be verified as to authenticity of source.

(2) The patient and physician should be advised about the existence of computerized data bases in which medical information concerning the patient is stored. Such information should be communicated to the physician and patient prior to the physician's release of the medical information. All individuals and organizations with some form of access to the computerized data bank, and the level of access permitted, should be specifically identified in advance.

(3) The physician and patient should be notified of the distribution of all reports reflecting identifiable patient data prior to distribution

of the reports by the computer facility. There should be approval by the physician and patient prior to the release of patient-identifiable clinical and administrative data to individuals or organizations external to the medical care environment, and such information should not be released without the express permission of the physician and the patient.

(4) The dissemination of confidential medical data should be limited to only those individuals or agencies with a bona fide use for the data. Release of confidential medical information from the data base should be confined to the specific purpose for which the information is requested and limited to the specific time frame requested. All such organizations or individuals should be advised that authorized release of data to them does not authorize their further release of the data to additional individuals or organizations.

(5) Procedures for adding or changing data on the computerized data base should indicate individuals authorized to make changes, time periods in which changes take place, and those individuals who will be informed about changes in the data from the medical records.

(6) Procedures for purging the computerized data base of archaic or inaccurate data should be established and the patient and physician should be notified before and after the data has been purged. There should be no commingling of a physician's computerized patient records with those of other computer service bureau clients. In addition, procedures should be developed to protect against inadvertent mixing of individual reports or segments thereof.

(7) The computerized medical data base should be on-line to the computer terminal only when authorized computer programs requiring the medical data are being used. Individuals and organizations external to the clinical facility should not be provided on-line access to a computerized data base containing identifiable data from medical records concerning patients.

(8) Security

A. Stringent security procedures for entry into the immediate environment in which the computerized medical data base is stored and/or processed or for otherwise having access to confidential medical information should be developed and strictly enforced so as to prevent access to the computer facility by unauthorized personnel. Personnel audit procedures should be developed to establish a record in the event of unauthorized disclosure of medical data. A roster of past and present service bureau personnel with specified levels of access to the medical data base should be maintained. Specific administrative sanctions should exist to prevent employee breaches of confidentiality and security procedures.

B. All terminated or former employees in the data processing environment should have no access to data from the medical records concerning patients.

C. Involuntarily terminated employees working in the data processing environment in which data from medical records concerning patients are processed should immediately upon termination be removed from the computerized medical data environment.

D. Upon termination of computer service bureau services for a physician, those computer files maintained for the physician should be physically turned over to the physician, or destroyed (erased). In the event of file erasure, the computer service bureau should verify in writing to the physician that the erasure has taken place. (IV)

*These citations refer to the *Principles of Medical Ethics* which may be found in the rear of the 1987-88 *Pictorial Roster* of the Medical Society of Delaware.

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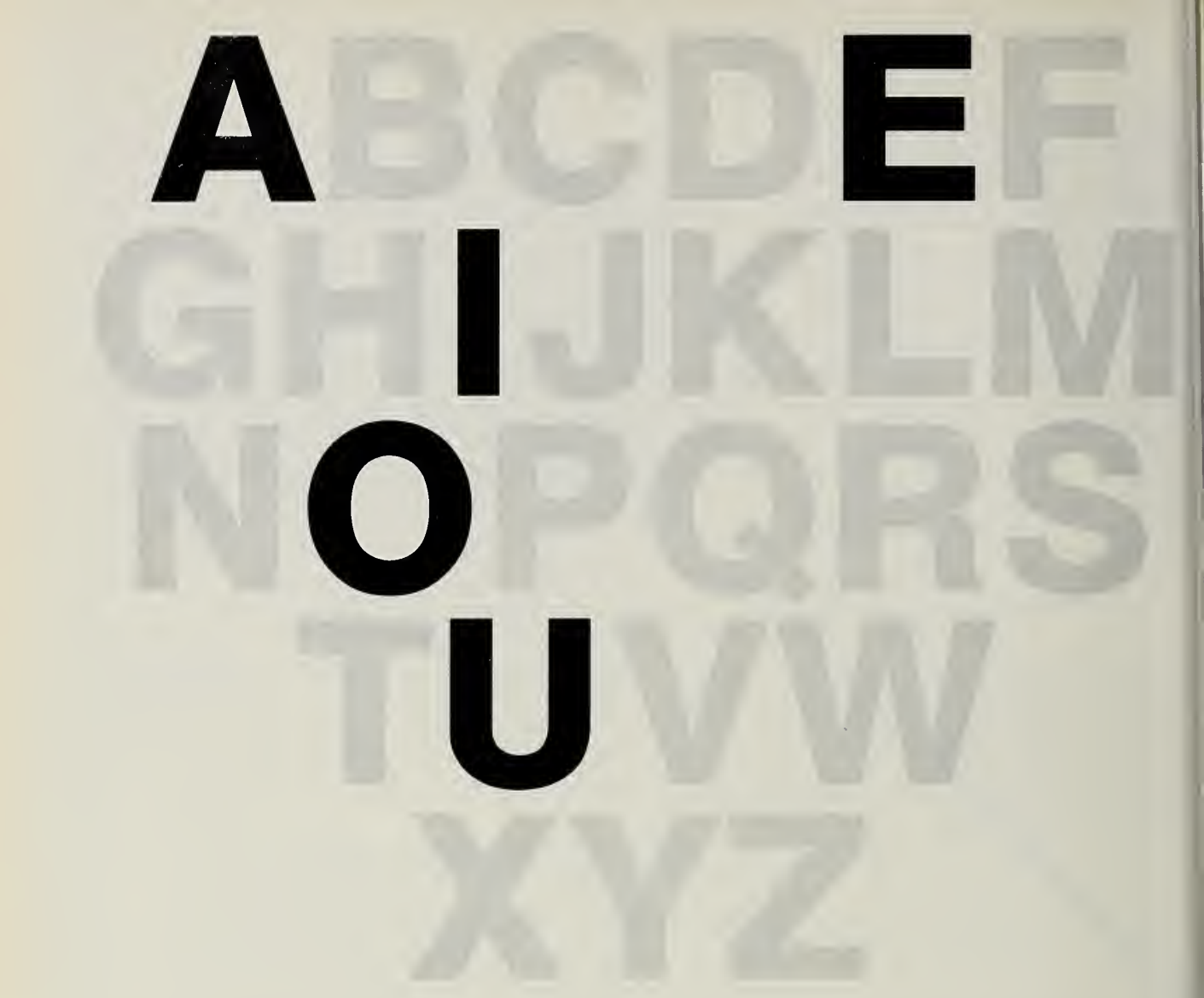

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Editorials

NEGLIGENCE IN PSYCHIATRIC PRACTICE

In the January, 1987 issue of the *Delaware Medical Journal,* Dr. David Raskin wrote an editorial entitled, "Involuntary Commitment in Delaware: Never the Same Again?" (59:29-31). In this article, Dr. Raskin emphasized the issue of the predictability of dangerousness in psychiatric practice. Unfortunately, the defense in many malpractice cases rests upon the issue of predictability of dangerousness, and ignores the negligence in the professional practice which contributed to the third party injury. Usually, it is the third party that brings the suit, as in this case, rather than the patient or family of the patient whose relapse into serious illness preceded the dangerous behavior.

In the case from Delaware State Hospital, which finally came to trial after nine years in November of 1986, there were three defendants: the admitting psychiatrist on the unit of Delaware State Hospital from which the patient was discharged; the Clinical Director who had been delegated clinical responsibility for the unit to which the patient had originally been admitted as well as for the unit to which he was transferred and later discharged; and the Medical Director, who had overall responsibility for the policies and professional practices at the Hospital. A particularly pertinent point was the fact that the physician who had discharged the patient was practicing at Delaware State Hospital under a limited license which required that he work under the supervision of the Medical Director.

The Delaware psychiatric community was particularly distressed by the verdict which found only one physician negligent. He was not able to have malpractice insurance because of his limited medical license.

The plaintiff argued the case on the basis of a review of the history of the medical treatment of the patient over the course of ten years, which involved a series of ten or 12 admissions either to Delaware State Hospital or a Veterans Administration Hospital. The plaintiff was the widow of the man killed when the patient, in a recurrence of acute psychosis, rammed the victim's car on Route 141 in New Castle County.

At that time many members of the Wilmington community were concerned over the policies which the Delaware State Hospital administration was pursuing in an attempt to keep down the inpatient population of the institution. Of particular concern to many professionals was the fact that patients would be discharged to outpatient treatment but the full schedules of the Mental Hygiene Clinics would not permit the patients to be seen in the first days after release from the hospital. This is the critical period for adjustment of medicines and relieving of patient anxiety. A patient of a private practicing psychiatrist in Delaware would be seen soon after discharge from a psychiatric inpatient facility. The question of whether or not the people of the State of Delaware through their state government have adequately supported a comprehensive network of psychiatric services, allowing for sufficient stay at Delaware State Hospital under therapeutic conditions and a strong social support system at the time of discharge, is the subject of another discussion.

At this time, I want to emphasize the factors of alleged negligence of psychiatric practice, which were the bases of the plaintiff's case. The patient received 20 mg of Navane t.i.d. on admission. On the third day, in accordance with general practice

at the hospital, he was deemed competent to sign a voluntary admission, which relieves the hospital of the necessity of pursuing the involuntary commitment procedure under which he had been admitted. The voluntary papers which the patient signed stated that he would remain until the doctors thought he had reached the maximum benefit from treatment, or else he would give four days notice in writing of his wish to be discharged against medical advice. The day after he signed these papers, for reasons which are not stated in the medical record, the attending psychiatrist increased his dosage of Navane to 30 mg t.i.d., a significant increase.

Several days later, the patient was transferred to another hospital unit under the care of the defendant psychiatrist who, without consulting the patient, changed his medication order from Navane to Thorazine. The psychiatrist's explanation was that he preferred Thorazine to Navane in dealing with psychiatric disorders. The patient's reaction was to make it adamantly clear to the nurse who offered him the change of medication that he had no intentions of taking Thorazine because he had severe reactions on the skin when he went out into the sun. Since the patient was over six feet tall, he could be rather intimidating, and his action led to a conference with the psychiatrist who returned to the original 90 mg daily of Navane.

In a matter of a day or two the patient submitted his demand for discharge in writing; four days later he was brought before a discharge conference and arrangements were made for his discharge. The hospital records do not document what transpired in the discharge conference. No evidence was given that the issue of the patient's readiness for discharge was discussed or that there had been any consideration of his previous hospital admissions and the multiple acts of a dangerous nature which the record revealed had been present on at least four previous admissions.

A review of previous hospitalizations in the Veterans Administration indicates that on at least one occasion when strong aftercare social support arrangements were set up, the patient adjusted well and seemed to be making progress in control of his schizophrenia and on the way to rehabilitation.

In the trial it was argued that since he was on a

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voluntary admission (which had replaced his emergency commitment status) the hospital had no alternative but to discharge him since he was not actively psychotic at the time of the discharge meeting. This certainly is not a valid argument. The issue of dangerousness and competence should not have been decided by the medical staff. Since he had been dangerous at the time of admission and since there were doubts as to his compliance with his treatment regime, the issue should have been referred to the court for judicial disposition.

At the time of discharge the patient was given medication sufficient to take Navane 90 mg daily for 30 days. Usual practice procedures in this community would have been to monitor his medication and reduce it to a lower maintenance dose as he went into remission from his acute psychotic phase. The discharge of a patient on 90 mg of Navane with no follow-up for 30 days was a major issue of medical negligence.

The object of any medical treatment is to diagnose the problem, and to provide the treatment best calculated to remove or control the problem and to enable the patient to have a minimum of disability. In the case of this patient, it was clear from his past record that he became dangerous when he relapsed, even though prior to this

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hospitalization he had never killed anybody.

The subject of negligence in psychiatric practice is most often highlighted in those instances in which a patient becomes dangerous. Unfortunately, there are no documentations of violence prevented by good psychiatric treatment, but most of us who have practiced psychiatry can cite many psychiatric illnesses in which possible death and violence have been averted by timely and appropriate intervention.

In the case under discussion, it was argued that psychiatrists cannot predict violence. It is true that psychiatrists cannot predict violence. It is also true that psychiatrists are similarly handicapped when it comes to predicting nonviolence in the face of a pattern of several years' standing of violent behavior at times of recurrence of acute psychosis. It was the judgment for the plaintiff in this case that it was gross negligence on the part of the physician at Delaware State Hospital to allow a patient who had been admitted to the hospital because of violent behavior associated with the recurrence of his illness to sign himself out after being transferred to a voluntary status, instead of referring the issue to the courts for a decision on dangerousness when the patient had shown no indication of enough insight to cooperate with his own treatment.

It was negligent to discharge the patient on such a large dose of psychotropic medication, without making provision for a follow-up visit with the intention of decreasing his medication at the earliest possible date.

It was negligent that no effort was made to establish a long term plan for the management of his illness and for the maximal protection of the patient from the immediate discomfort of a relapse.

The jury found in favor of the plaintiff, asserting medical negligence on the part of the discharging psychiatrist. But through some legal technicality, the Medical Director and Clinical Director who dictated the policies under which the discharging psychiatrist worked were not found guilty.

V. Terrell Davis, M.D.

THE PRESCRIBING HABITS OF DELAWARE'S PHYSICIANS

The legislation which permits generic substitution in Delaware also mandates periodic review to see if substitution saves consumers money. A second such study was recently performed under the aegis of Dr. Maven Myers, Professor of Pharmacy Administration at the Philadelphia College of Pharmacy and Science, the person who also performed the first study ten years ago. For

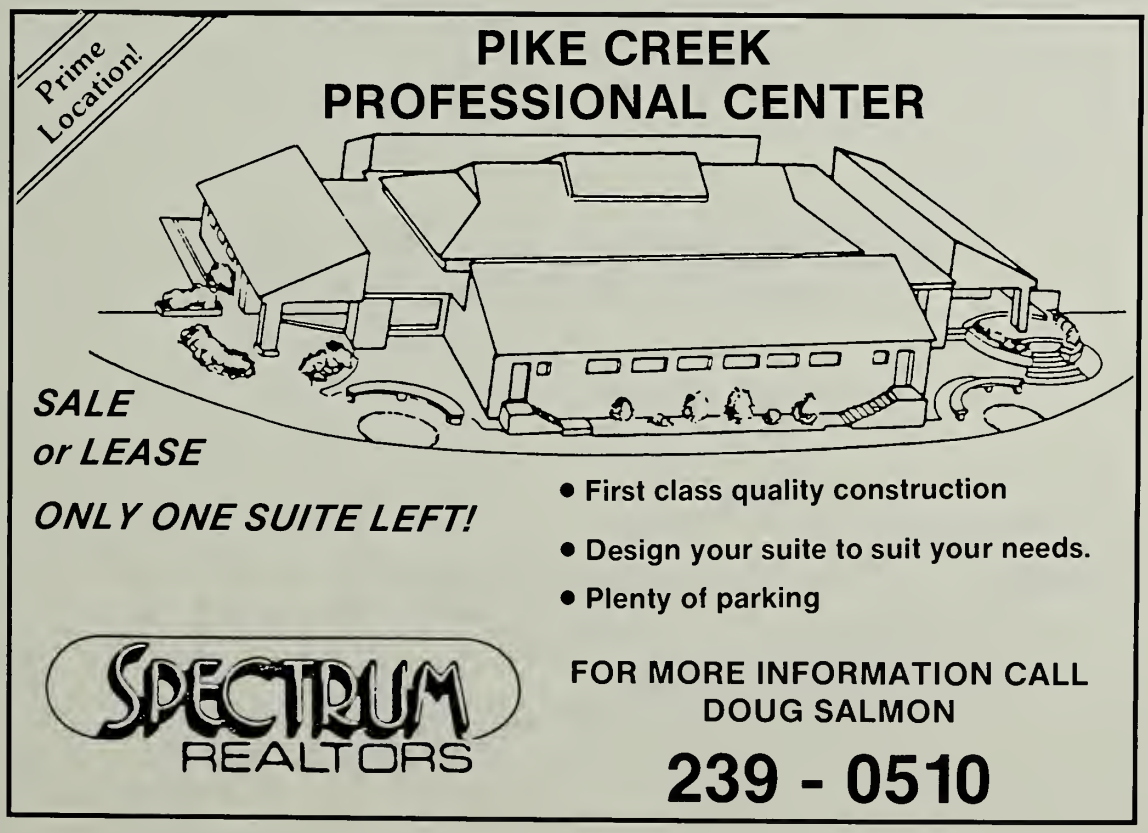
each of 15 drugs, five prescriptions were filled in 30 different community pharmacies. Last time, only ten drugs were evaluated, but since five of those ten are no longer in frequent use (meprobamate is one), so five new ones were added. Comparison of the recent findings with those of ten years ago reveals several interesting findings.

Pharmacists do not have to dispense a generic if they do not wish, even if one is commercially available. When a generic is available and authorized, it is now provided to the patient 68% of the time versus 56% in 1977. The provisions by the Code for this option are theoretically advantageous either to the patient or to the pharmacist, but the option means that physicians have no idea whether or not their patients will actually receive a generic substitute. In fact, a third of the time they will not.

Surprisingly, for five of the 15 drugs studied, there is no significant price difference between the generic and the trademark medicine, and for two frequently prescribed medications, ibuprofen 400 mg and penicillin V 250 mg, the trademark versions actually cost less!

It is not surprising that in the past decade the prices of both branded and non-brand name pharmaceuticals have increased, but the percentage increase in the cost of the generics is much higher, making them not nearly the bargains they were when the substitution law was passed. One interpretation of this cost increase is that manufacturers of generics have had to improve quality in order to compete as substitutes for brand names and so had to take steps, costly steps, to improve the reliability of their products. I wonder if the increase was not also made for them to profit as much as possible from the prescriptions being handed to them without effort on their part by physicians being trained to write for generics; the generic manufacturers have no pact to save Delaware's consumers as much money as possible.

Physicians now allow substitution 53% of the time; only 38% did so ten years ago, and about 60% of medications being written for are available from multiple sources, compared to only 47% ten years ago. Still, of all the prescriptions studied, the prescribers withheld authorization to substitute 35% of the time even though a generic is available. This privilege has now been taken away in Delaware for Medicaid patients; physicians must now write that a trademark product is "medically necessary," a Medicaid ruling in conflict with the



present Delaware statute which allows a signature on the appropriate line ("Dispense as written") to accomplish the same thing.

One of the reassuring findings is that the physicians studied did not change their prescribing habits for patients whose medications are paid for by third parties. The physician's own earnings are at risk if their drug budget is overspent, so I wonder if this was a conscious, ethical decision, or whether primary care physicians contracted to HMOs as PCPs (primary care providers) are already resigned never to receive the 20% withhold from their designated capitation, or whether most of us have not yet learned the new economic facts of our lives.

The evaluation of third party prescriptions performed ten years from now is very likely to show different data, as Total Health Plus has recently directed its physicians to allow substitution whenever possible. Their directive suggested it was of probable benefit to patients for physicians to write prescriptions with a tradename, but allowing substitution rather than writing it for the generic directly, a habit I have always tried to encourage. A startling if true reason for this was suggested: writing a brand name and then allowing substitution requires the pharmacist to use the best quality generic available from a special FDA-provided list which tabulates the quality of available generics. A prescription written directly for the generic drug does not mandate the same guarantee. If it is true that writing Lasix or Motrin and then allowing substitution may indeed get a patient a higher quality generic substitute, then the very folks who are encouraging us to substitute are admitting that the quality of trademark medications is quite likely higher than non-branded versions of the same drug.

The drugs for which the study showed savings may accrue if the pharmacist elects to substitute are: amitriptyline 25 mg, amoxicillin 250 mg, diazepam 5mg, dipyridamole 50 mg, furosemide 40 mg, hydrochlorothiazide 50 mg, isosorbide dinitrate 10 mg, methyldopa 250 mg, metronidazole 250 mg, and propoxyphene compound 65. Savings may not be as pronounced or may not exist for different dosages, and may disappear altogether if few tablets or small quantities are prescribed. For 25 mg amitriptyline in this study, the savings of generic versus brand averaged 12 cents per dose; for hydrochlorothiazide, it was five cents. The highest differences observed were for metronidazole.

All of this leads me to the dreary conclusion that physicians who wish to do the best for their patients would have to price the cost of a specific prescription, specific quantity, and specific brand at the particular pharmacy their patients are planning to visit.

Furthermore, if the difference in a brand name and a generic is only a penny or two a dose, brand name prescribing may still be preferable despite the pressures against it. Those who deny this should be able to say they also do not care at all what brand toothpaste, shampoo, soap, automobiles, or clothing they buy. Are medications truly less important?

Bernadine Z. Paulshock, M.D

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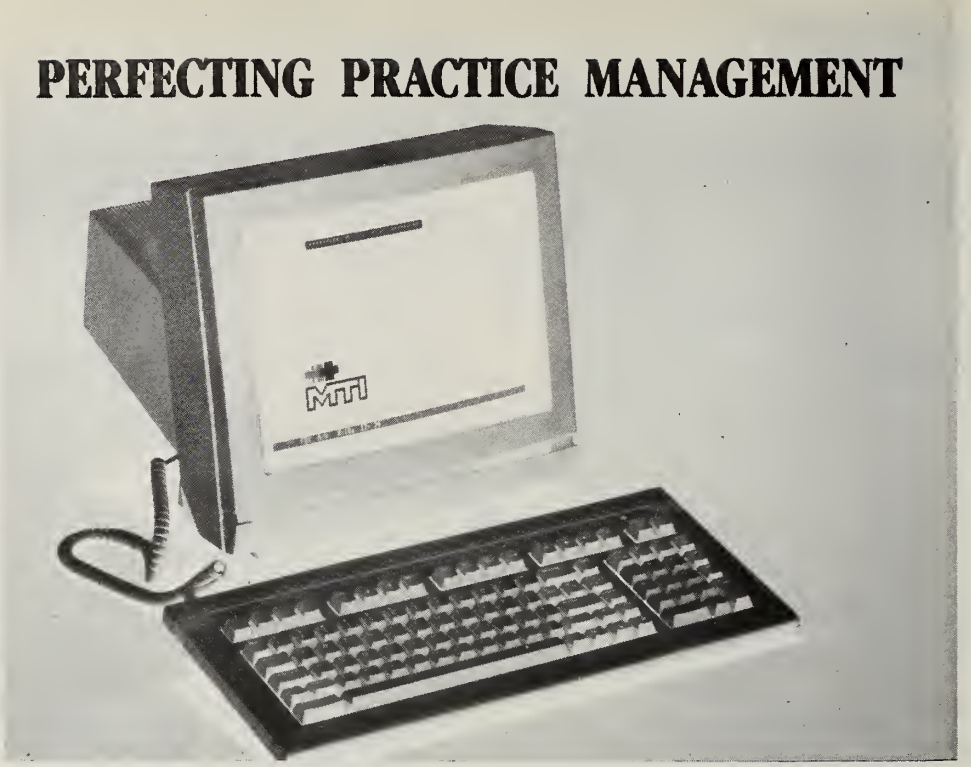

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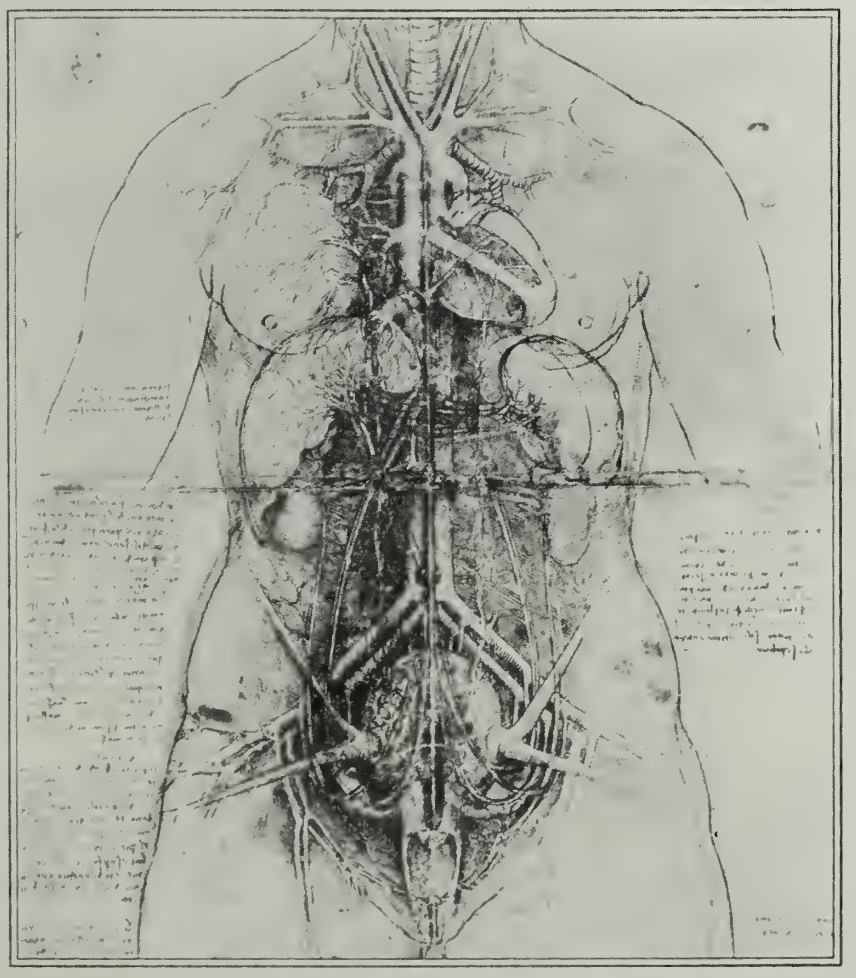

Anatomy of an Adult Woman, by Leonardo daVinci

This drawing, done around 1500, shows the thoracic and abdominal organs of an adult woman and the arteries and veins running to them. While the representation of liver, spleen, kidney and uterus are largely correct, many of the vessels show an erroneous course.
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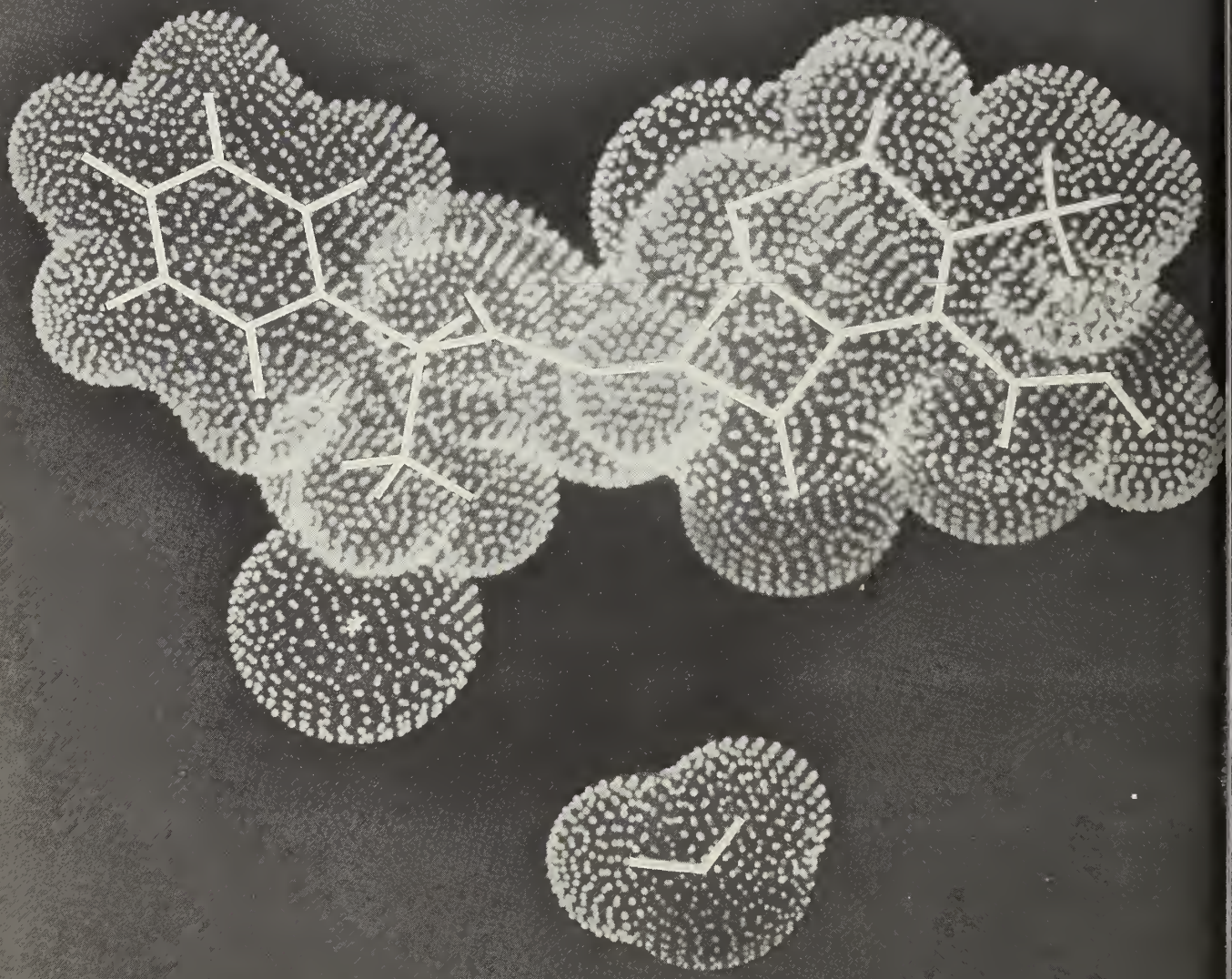

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PART II

REPORTS OF SPECIAL COMMITTEES

COMMITTEE ON AGING

The Committee on Aging became very active during the past year. There was active participation from many members and several excellent programs evolved.

A program entitled "A Guide To Services For Older Delawareans" was given during a Tuesday morning conference at the Academy of Medicine in conjunction with The Medical Center of Delaware. This program featured Ms. Eleanor Cain, who is the Director of the Division of Aging for the State of Delaware. It included commentaries from social workers, representatives of the Visiting Nurse Association, and pharmacists, in order to inform physicians of programs presently available for the elderly in the State of Delaware.

Another program was initiated which was entitled "Health Care Issues For The Elderly." This was a one-half day program which was targeted at elderly citizens. It included both legislative and medical topics. The participants and their topics were all felt to be excellent; however, community participation was somewhat less than optimal.

In addition, a geriatric seminar is planned in conjunction with The Medical Center of Delaware for December 1, 1987. This will be a half-day program aimed at current topics in geriatrics for the practicing physician.

Our primary goals for the coming year will include development of a closer liaison with the Delaware chapter of the AARP. We also plan to repeat both of the programs that were offered this year with stress on improved promotion of these programs and increased public participation and awareness of the Medical Society's concern for the problems of the elderly.

Robert G. Altschuler, M.D.
Chairman

(The report was filed with a commendation to Dr. Altschuler and his committee for developing an active and innovative program.)

ALTERNATIVE METHODS OF HEALTH CARE DELIVERY AND HEALTH PLANNING

This committee largely serves at the discretion of the President and the Board of Trustees of the Medical Society of Delaware. There have been no meetings of this committee since December 13, 1984, nor have there been any requests for the committee to meet. It is recommended by the Chairman that this committee be dissolved.

Anthony L. Cucuzzella, M.D.
Chairman

(The report was referred to the Board of Trustees for reconsideration of the mission of this committee.)

ANCILLARY PROFESSIONALS

There have been no formal meetings during the past year of the Ancillary Professionals Committee or its subcommittees, which at present include the following: Certified Nurse Anesthetists; Licensed Clinical Social Workers; Nurse Practice Act; Optometrists; Physician Assistants; and Podiatrists.

At the present time, the committee is studying the issue of professional licensure, namely does the state license people for the protection of the public or does it license individuals so that they might be eligible for third-party reimbursement and increased personal status?

Meetings will be held as required by legislative initiatives.

Ignatius J. Tikellis, M.D.
Chairman

(The report was filed with approval of the recommendation that this committee be enlarged and become more active. The Reference Committee recommended that psychiatrists, ophthalmologists, and other physicians who have concerns regarding ancillary professionals bring these concerns to the attention of the committee.)

BYLAWS COMMITTEE

A meeting of the Bylaws Committee was held on September 28, 1987, at the Delaware Academy of Medicine Building in Wilmington. Six of seven members of the committee were present.

The first item discussed was a resolution from the Society's Board of Trustees in support of de-unifying membership with the AMA.

De-unification would require a Bylaws change deleting Section 1 of Article III (Membership) of the Society's Bylaws. This section states:

Membership in the American Association or the American Osteopathic Association is mandatory for all Medical Society of Delaware members.

According to Article XIII, Section 16, of the Society's Bylaws, all proposals for amendments to the Bylaws shall be submitted to the Bylaws Committee for consideration and recommendation.

The following recommendation was unanimously adopted by the committee following discussion of the issue: That the resolution not be adopted and that the Society's Bylaws not be amended at this time.

The next topic discussed was the procedure to be followed when an office becomes vacant due to the death, resignation, removal, or disqualification of any officer. The Bylaws now provide that the President may, with the confirmation of the Board of Trustees, fill the vacancy by appointment. The Bylaws do not limit the powers of the appointee in any manner. Therefore, if the appointee is the President-Elect or Vice President, he or she would have the right of succession without having been elected by the House of Delegates. It was also noted that the Bylaws at present state that the Vice President and not the President-Elect is to succeed the President upon the death, resignation, etc., of the President. The Bylaws Committee recommends that the Bylaws be amended as follows: Strike Section 4 (Vacancies: How Filled) of Article V (Officers) in its entirety and substitute in lieu thereof the following:

Section 4
VACANCIES: HOW FILLED

If the President dies, regsigns, or is removed, or becomes disqualified, the President-Elect shall succeed to the office vacated with all the prerogatives and duties pertaining to the office of President and shall, for the unexpired term, also retain all the prerogatives and duties pertaining to the office of President-Elect. If the President-Elect dies, resigns, is removed, or becomes disqualified, the Vice President shall succeed to the office of President-Elect with all the prerogatives and duties pertaining to the vacated office. If the office of Vice President becomes vacant for any reason, it shall remain vacant until the next session of the House of Delegates. Vacanies created by death, resignation, or removal of officers and vacancies in contingencies not herein provided for shall be filled by the President and confirmed by the Board of Trustees for the unexpired portion of the term.

Also suggested was revision of Article V to provide that the Vice President may officiate during the absence of the President and the President-Elect. The Bylaws Committee recommends that Section 7 (Vice President) of Article V (Officers) be amended as follows: Add the words "and may officiate for him during the absence of the President and the President-Elect" after the word "duties" at the end of the first sentence.

In addition, the Bylaws Committee recommends that Section 4 (Conduct of Business) of Article VI (House of Delegates) be amended to provide that the President-Elect rather than the Vice President shall preside over the House of Delegates in the absence of the President and the Speaker.

Lastly, the Bylaws Committee recommends that Section 3 (Meetings) of Article VIII (Board of Trustees) be amended to provide that in the absence of the President the President-Elect shall preside and in the absence of the President-Elect the Vice President shall preside.

A summary is attached showing both the appropriate sections of the present Bylaws and the proposed changes.

Dene T. Walters, M.D.
Chairman

(The report was adopted.)

CHARITABLE SERVICES

The Charitable Services Committee has worked this year on the development of programs for the delivery of medical care by members of this Society both on an international and domestic basis.

From the international standpoint, the committee has met on two occasions and discussed the possibilities of delivery of health care both on a direct basis as well as through improving medical care through educational training of available health care professionals in developing countries.

A dinner meeting was held with Dr. Marian Scena, who gave an extremely interesting lecture on the delivery of health care by the Medical Missionaries of Mary in Kabanga Hospital in Tanzania. It was felt that the needs in Kabanga Hospital would require a one to two-year commitment and that short-term assistance, while valuable in disaster situations, would be less helpful because of cultural differences and environmental difficulties. She suggested that possibilities for short-term involvement would be a larger institution where there is a need for surgeons, or the Flying Doctors, where possible relief for physicians on home leave would be entertained, or the program that is currently being developed by the Eastern Virginia Medical School for medical care in Lebanon and other Mideast countries.

Contact was made with Dr. James C. Cobey of Washington, D.C., to investigate the possibilities of an alliance with organizations such as Health Volunteers Overseas as well as Orthopedics Overseas. Both of these organizations are private voluntary groups formed to upgrade, broaden, and strengthen the skills of health professionals in developing countries. The concept behind this is that many countries in the third world lack suitable numbers of appropriately trained health professionals, and those professionals who are trained in the United States are often exposed to concepts and techniques that have little or no applicability in their native country. Thus, volunteers would train individuals in their native environment in the use of appropriate technology that is locally available and utilizable. Volunteers in this type of program serve usually for a period of two to six weeks, which would be ideal for members of the Society.

Continuing work in these areas is being investigated by the committee, and it is anticipated that during the coming year some form of program will be established. Several members of the committee have already committed to individual efforts in Africa and South America.

From a domestic standpoint, Chaplain Lynwood Swanson has developed a program in cooperation with Mr. Steve Autman, Executive Director of the Claymont Community Center. This program will be directed toward providing primary care services in underserved neighborhoods in the Claymont area. The Claymont Community Center will be the site several days a week for clinical services such as pediatrics, geriatrics, and obgyn. Volunteer physicians will be enlisted to provide primary health care and education. It is felt that this program, which has the sponsorship and approval of the Board of Trustees of the Medical Society of Delaware, can be a model for centers in other areas of need in the state. The problem of medical malpractice insurance coverage is being worked out with Medical Society of Delaware Insurance Services and should be in place by the time of the annual meeting.

It is the stated aim of this committee to develop a mentality amongst members of the Society of giving and rendering medical care to those who are underserved and underprivileged, both domestically and internationally. The interest and support of the members of

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this committee is gratefully appreciated as is that of Chaplain Lynwood Swanson and Dr. Robert Frelick, who have expended extraordinary efforts in developing the Claymont project. The current proposal for this project follows.

Peter R. Coggins, M.D.
President

(The report was filed with the following attachment.)

CLAYMONT PROJECT PROPOSAL
HEALTH SERVICES

I. ADULT HEALTH SERVICES

This project hopefully will be jointly sponsored by the Medical Society of Delaware and the Claymont Community Center with the cooperation of the Division of Public Health, the Delaware State Dental Society, the Delaware Nurses' Association, voluntary health agencies in Delaware, and cooperating individual optometrists and podiatrists. The "Adult Health Services" (AHS) will supplement the pediatric services now provided.

II. PURPOSE

The AHS's goal is to promote improved health for adults in the Claymont area especially those who have no medical coverage or limited resources for medical/health care.

This is to be done by supplementing and complementing existing community resources for health promotion and by filling gaps in services without duplicating existing programs. Private medical offices, hospital clinics, non-profit health agencies, and public health programs will be used for referral purposes.

Continuity of care will be emphasized.

The activities will include:

1. An effort to respond to individual health concerns of the participants in the Claymont Community Center AHS. This may include acute but minor problems such as sore throats, bronchitis, feeding problems, skin rashes, and sore feet.
2. Screening histories and tests to determine health risks.
3. Assessment of physical, nutritional, emotional, and socio-economic status in order to counsel individuals about when, how, and where to seek professional help.
4. Physical examinations as needed for school, etc.
5. Assistance when situational, financial, and/or transportation limitations become barriers to health services.

(The AHS will not be able to fill all health care gaps or answer all health problems.)

III. CRITERIA FOR ELIGIBILITY

Adults over 18 years of age will be encouraged to participate if they do not have an existing source of medical care, or if so, are unable to afford needed services.

The AHS is designed to help those with limited resources use the current health care system. Administrative review of individual resources and needs will be used to assign reasonable payment potentials.

Priority will be given to residents of New Castle County northeast of Wilmington but if appointment times are available, residents outside of the area will be accommodated.

There will be no distinctions made on the basis of race, sex, religion, or life styles.

Those with a private physician may participate in the screening program with the understanding that the results will be forwarded to their physicians. All who need more than the limited help and care available through the Community Center facility will be referred to an appropriate facility. This will include private physicians who have agreed to provide such services in accordance with a graduated fee schedule, based on individual resources and needs, as developed by the Community Center staff. Referral information will be available through the AHS.

IV. SERVICES PROVIDED THROUGH THE AHS

Screening history using a questionnaire to be filled out by the applicant. That information will provide a basis for a health risk appraisal. Depending upon the risks noted in the history, a number of the following screening techniques will be chosen.

Weight, height; blood pressure; hearing and/or visual acuity; observation of locomotor status; skin; oropharynx, and teeth; palpation of the breast, abdomen, testes (in men); pelvic (in women) with a Pap smear and rectal exam.

Additional tests could include: a tuberculin skin test,

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Transportation: It is planned to have a van available to help those who cannot get to the Center or who need such aid in order to respond to a referral appointment made by the Center.

The Center will have a list of community resources and referral potentials including private physicians. The latter will probably be from a rotating list of available physicians and other health professionals who have agreed to respect the Center's sliding fee scale.

Individuals and families will be encouraged to have personal physicians to provide primary health care and to act as guides through the health system maze for additional care as needed. The Health Services should be looked upon as a resource for the people of Claymont similar to that provided through occupational medical departments in some industries.

Pharmacy services will be provided on referral if not available in the Community Center. Generic drugs will be encouraged.

Each person will have a record for administrative as well as clinical purposes. Except for "first aid" or "acute care" visits, there will be an initial screening history and assessment followed by a counseling session in which the risk items will be reviewed. If health behavior is a problem, or information is needed about a health concern, referral to an appropriate resource will be made. If additional studies or treatments are indicated beyond the ones available at the Center, referrals will be made.

Fees will be assessed according to the sliding scale developed by the Community Center staff.

Those using the AHS will be provided with a limited medical record which can be kept by the patient and taken with them at the time of referral and for return appointments. The complete record will include identifying data, a problem list, medications, summary of risk factors, and positive findings from the screen. In addition the clinic record will have the screening history and assessment results as well as interval illnesses, progress notes, and referral information.

A separate financial and appointment record will be kept.

Whenever possible, an appointment schedule will be used. Individuals will be assigned the same staff whenever possible. Group sessions will be used when feasible especially to help those wanting additional information, for example, on dietary and nutritional issues.

Evaluation: Quality assurance reviews and audits will be invited from the Medical Society and/or the Division of Public Health unless an appropriate outside organization will offer its services.

Future plans: To use information for this system to replicate or develop Health Services in other communities in Delaware.

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CULTURAL AND HISTORICAL

Tentative plans for the Medical Society of Delaware's upcoming 200th Anniversary were made. The following suggestions will be considered by the subcommittee involved in the planning:

1. One big celebration and other minor events throughout the year.
   a. Make the Annual Meeting, with its built-in audience, the focal point for the 200th.
   b. Cocktail party on date of incorporation, May 13th.
2. Monologue - Professor J. Soles.
3. Issue of the *Delaware Medical Journal* devoted to the 200th Anniversary.
4. Develop a new history of the Medical Society of Delaware.
5. Historical Society be approached to put together an exhibition at Historical Society Building.
6. Expand on the Tilton story.

Another meeting is planned for January.

Robert B. Flinn, M.D.
Chairman

(The report was filed.)

ENVIRONMENTAL AND PUBLIC HEALTH

The Environmental and Public Health Committee studied a wide variety of issues this past year. Guests at our meetings included Mr. H. Wayne Ashby, Director of the Water Resources, Division of the State Environ-

mental Control Agency; Dr. Marjorie P. Kraus, Virologist; Dr. William H. Mitchell, Civil Engineer; Dr. John F. Reinhardt, Infectious Disease Division of The Medical Center of Delaware; members of the faculty of the University of Delaware; and others.

Problems with the Kent County Sewage Treatment Plant were investigated at a meeting that included several members of the Division of Water Resources. It was our conclusion that there is an urgent need for more inspectors to oversee Delaware's more than 40 sewage treatment plants. Mr. H. Wayne Ashby of the State Environmental Control Agency, claims that his budget allows him to retain only two inspectors for the entire state. This is grossly inadequate. The state legislature has recently taken action to improve the state standards for treatment of waste water and sludge, but without an adequate complement of inspectors the standards will not be enforced.

The committee wishes to commend Dr. A. Robert Masten of Milford on his tireless efforts to protect the land and waters of southern Delaware from pollution. The emptying of sewage into the Murderkill gut has been of particular concern to Dr. Masten. The committee would urge the state to move the effluent pipe from the Kent County sewage treatment plant further out into the Delaware Bay, where the greater volume and flow of water would allow for proper dispersal of effluent, and would discourage settling and bottom accumulation and pollution.

The committee also studied the problem of inadequate health education in Delaware. We were encouraged by the September 23rd decision of the State Board of Education to make Health Education mandatory in Delaware's public schools, grades K-12. The committee intends to take an active part in assisting local school districts with the carrying out of this policy. The committee would urge Dr. Russel Jones, President of the University of Delaware, to include health education courses in the University's program of education of elementary school teachers. Our state's health education program will be only as good as the preparation of our teachers.

At our October meeting, the committee was privileged to hear an excellent presentation by Dr. John J. Reinhardt on the epidemiology and treatment of Lyme disease. This tick-borne spirochetal disease, which can cause serious arthritides and CNS problems, has been on the increase in this state in the past five years, probably related to migrations of the white-tailed deer population. The committee feels that the community would be well served by increasing physician and public awareness of the disease with a well publicized evening lecture on the subject in early spring before the onset of the tick season.

Attendance at meetings of this committee has been good, and participation by members of the committee has been active and spirited. As chairman, I wish to extend my sincere thanks to the committee members and to encourage them to continue their interest and involve-

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ment in the health of our populace and of our environment.

Diana Dickson-Witmer, M.D.
Chairman

(The report was filed. The Reference Committee noted that the Committee has also studied the problem of pollution of the Delaware Bay.)

ETHICS

An ad hoc committee on ethics was appointed by Dr. Peter R. Coggins in January 1987. It has met seven times and has other meetings scheduled. Because of the number of ethical questions, many related to increasingly sophisticated medical technology, it was anticipated that the committee would develop guidelines to help Society members resolve ethical challenges in practice. However, it soon became obvious that there was a reluctance to pontificate, especially since most issues were being resolved quietly between physicians and their patients. Therefore, the committee adopted an educational approach.

A survey of the organized health care providers, hospitals, HMOs, and nursing homes in Delaware indicated that they basically agreed with the Current Opinions of the Council on Ethical and Judicial Affairs of the AMA. It was also determined that most of the hospitals in the state had ethics committees, but most were not very active. In order to stimulate more interest, an ethics page was started in the *Delaware Medical Journal* to help inform physicians of the AMA's interpretations of ethical principles and to sensitize members to ethical problems. There was a subjective impression that a significant number of malpractice actions might have been avoided by a greater sensitivity to ethical issues.

There were very few spontaneous requests to the committee from either physicians or hospitals. Therefore, in the early summer a number of ethical questions were sent to the membership. There was a surprising 44% response. The conclusions are due to be published in the October issue of the *Journal*. Comments and responses to the questions showed significant variations and/or interpretations of many ethical issues.

The committee has learned that ethics committees will be required by the JCAH. They will be asked to have a written policy on resuscitation. The Medical Center of Delaware committee is in the process of establishing such a protocol by January 1988. Hopefully, that will provide a guideline that can be useful to other hospitals in Delaware.

In July, a question was raised about a physician's right to refuse to treat a patient suspected of having AIDS. The Medical Center is now struggling with this problem, which is multifaceted. The Board of Medical Practice has issued a general statement that in any emergency a physician should respond irrespective of the possibility of AIDS, but precautions should be taken by the health care providers. The latter was reinforced by a recent OSHA requirement. Hoped-for national guidelines now are being deferred to the states, leaving unanswered questions. The committee hopes to keep the membership informed of progress in that field.

In the meantime, hospital ethics committees should become functional. The Society's Ethics Committee is ready to assist and advise individual physicians and hospitals.

Robert W. Frelick, M.D.
Chairman

(The report was filed with commendation to the committee for a good start-up year in approaching a difficult area in a difficult era.)

HOSPITAL RELATIONS

Meetings of the Committee were called on order from the chairman.

The members of the committee, representing physicians on the staffs of all the hospitals in Delaware, met to discuss the present climate between physicians and hospitals.

Problems common to both physicians and hospitals such as credentialing, malpractice, re-orientation of medical markets, and the changing climate of physician/hospital relations were discussed.

Thus far, a meeting between representatives of the boards and/or administrations of the hospitals and the physicians serving on the committee has not occurred. Future official contact between the two groups is in the opinion of the committee desirable, and the effort for future meetings should be pursued.

The service of the members of the committee has been greatly appreciated. They have served the Medical Society of Delaware in an admirable manner.

Albert Gelb, M.D.
Chairman

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(The report was filed with approval of the recommendation that there may be a need to redefine the purpose of the committee and the recommendation that the medical/dental staff of each hospital be encouraged to send a representative to the AMA Staff Section meetings.)

MATERNAL AND CHILD CARE

The Maternal and Child Care Committee continues in its efforts to develop a statewide perinatal record system. In Phase 1, a prenatal assessment form has been approved by the committee and will be reviewed with the obstetricians in each county in the near future. Phase 2 involves the development of standardized intrapartum and neonatal forms. These forms will be compatible with the statewide computer system collating data for research statistics and birth certificate information.

The committee is also concerned about the continuing problems of AIDS, adolescent pregnancy, and substance abuse in pregnancy. We request the support of the Medical Society of Delaware in the development of programs for public awareness and education.

Robert H. Radnich, M.D.
Chairman

(The report was filed.)

MEDICINE AND RELIGION

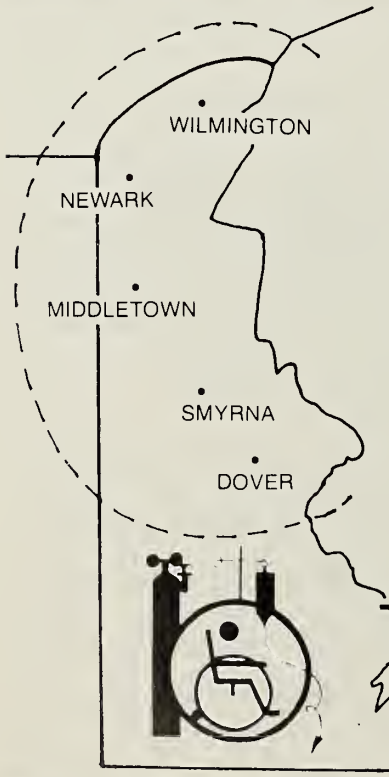
The committee and its advisory subcommittee have met a number of times and organized the spring and fall programs. The April 1987 physician/clergy breakfast was held at the A. I. du Pont Institute; it was attended by about 160 physicians and clergy and other interested persons. The topic of organ donation was addressed by a panel of distinguished speakers: Professor M. Williams on ethical aspects; Dr. Bruce Fellows, peripheral vascular surgeon, who has been involved in the preparation of organs for transplant; Reverend G. Howe from the Delaware State Legislative Committee on Organ Donation; Mr. T. Wilson, a father who participated in the organ donation program; and Mr. H. Serenbetz, the recipient of a heart transplant. Currently we are preparing for the upcoming November prayer breakfast when Reverend William Pindar with the use of clowning and pantomime will demonstrate how humor relates to the problem of pain.

The parent committee has been receiving invaluable assistance from the advisory subcommittee, which was approved in the summer of 1985 by the Board of Trustees of the Medical Society of Delaware and held its first meeting in November 1986. Its members come from different disciplines of the community and together contribute a wider scope. The subcommittee's efforts culminated in a brochure on organ donation that was distributed to those in attendance at the April 2, 1987, physician/clergy breakfast.

We hope that the Society's members find our spring and fall programs enjoyable.

Salvatore Muleh, M.D.
Chairman

(The report was filed.)



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MEDICO-LEGAL AFFAIRS

The Medico-Legal Affairs Committee, in association with the corresponding committee of the Delaware Bar Association, has drawn up a tentative new interprofessional code that is to be submitted to the respective boards of trustees.

One unfinished item has been the establishment of a review mechanism for disputes. There has been much discussion about this. It is hoped that this problem can be resolved and a recommendation passed on to the respective boards of trustees of the Medical Society of Delaware and the Delaware Bar Association in the fall of 1987.

John T. Hogan, M.D.
Chairman

(The report was filed.)

MENTAL HEALTH, ALCOHOLISM, AND DRUG ABUSE

The committee has had a continuing concern about the mental health and substance abuse services provided by the State. Unfortunately, there has been no progress in establishing a collaborative relationship between the State system of mental health care and the private sector of organized medicine. What has been disturbing is that there is no avenue through which we can provide input to the State system; informal contacts have been unproductive.

This committee was most alarmed to learn of the recommendations of a business-type survey of the State Hospital. The report which came indirectly to our attention practically denigrated the role of psychiatrists while treatment of patients was to be determined by non-professional managers or other non-physicians. With the approval of the Board of Trustees, an ad hoc subcommittee met with Secretary Eichler to voice our concern about patient care and to offer the cooperation of psychiatrists in the private sector. Although Secretary Eichler made no commitment, he conveyed the impression that he listened and that he heard us. Thus, we are encouraged to think that a door has been opened at least a crack.

Norman Taub, M.D.
Chairman

(The report was filed.)

PHARMACY

This year the committee addressed the "Drug Product Selection in Delaware - 1986" paper prepared for the Department of Health and Human Services, State of Delaware, by Maven J. Myers, professor of pharmacy administration at the Philadelphia College of Pharmacy and Science.

The Delaware Drug Product Selection Act allows substitution under certain conditions. The same Act requires that the Pharmacy Control Office determine what influence the Act has on the price of prescription drugs. An initial study was done by the Philadelphia College of Pharmacy and Science in 1977 for the Department of Health and Social Services.

The paper shows the current effectiveness of the Act according to the Philadelphia College of Pharmacy and Science (paper available in Society offices).

The Delaware Drug Product Selection Act appears to be accomplishing its goal of producing savings for Delaware drug consumers using the following drugs:

Amitriptyline 25 mg.
Amoxicillin 250 mg.
Diazepam 5 mg.
Dipyridamole 50 mg.
Furosemide 40 mg.
Hydrochlorothiazide 50 mg.
Isosorbide Dinitrate 10 mg.
Methyldopa 250 mg.
Metronidazole 250 mg.
Propoxyphene Compound - 65

Irving M. Berkowitz, D.O.
Chairman

(The report was referenced back to the Pharmacy Committee for clarification of the Drug Product Selection Act.)

PHYSICIANS' HEALTH

The Physicians' Health Committee met four times this past year, all meetings taking place at the Academy of Medicine Building in Wilmington. Proceedings at each meeting included presentation of new cases, review of selected active cases, and discussion of other matters pertinent to the committee.

The past year has been active, even though the number of cases was less than a year ago. The three new cases requiring intervention were complicated and required a great deal of time and effort. Two of the cases ended up with license suspension. These three cases, along with eight others, continue on active status. One case was moved to inactive status.

The problem of AIDS in practicing physicians was discussed at length. The committee concluded it can function as a treatment and counseling resource in such cases. In addition, a policy statement for the Society should be forthcoming. It is suggested that the Board of Trustee's deliberate the matter and that any policy include the Physicians' Health Committee as an integral part.

During the past year, due to the nature of our cases, there was a great deal of interaction with the Board of Medical Practice. Guidelines drawn up by the committee five years ago proved useful and effective. Legislation, particularly at the Federal level, makes our dealings with the Board of Medical Practice all the more important.

For next year, the committee intends to send a representative to the National Conference on the Impaired Physician to be held in Chicago. We also plan to be more involved in the direct treatment of impaired physicians.

Joseph E. DeLaurentis, M.D.
Chairman

(The report was filed.)

PRISON HEALTH

Last year, the Department of Corrections received a two-year accreditation for Delaware's seven prison health care facilities. This accreditation followed a

comprehensive week-long evaluation by the National Commission on Correctional Health Care, the same AMA-sanctioned organization which two years previously had refused to accredit the Delaware prison health care system because of substandard care they found in the system.

For some time now, the Prison Health Care Committee has felt that accreditation by the National Commission would be the most effective method to assure that acceptable medical care is being provided in our prison health system.

Since this accreditation has been received and since there has been a marked reduction in the number of complaints received by the Medical Society from the prisoners and from the community, there have been no formal committee meetings since our last report.

During the next year, the committee plans to continue to closely monitor prison health care in our state and become involved whenever there is evidence brought to our attention which may indicate substandard medical care in the system. We also will continue to encourage the Department of Corrections to establish the two-year accreditation by the National Commission on Correctional Health Care as an ongoing standard for the prison health care system.

John C. Sewell, M.D.
Chairman

(The report was filed with approval of the recommendation that the Prison Health Committee look into the problem of AIDS patients in the prison system and with a commendation for Dr. Sewell for having spearheaded the accreditation by the National Commission on Correctional Health Care.)

SCHOOL HEALTH

The School Health Committee held no formal meetings this past year.

However, members have monitored a number of issues with interest in areas such as seat belt requirements in school buses, smoking restrictions on students in public schools, AIDS education, and sex education in schools among others on which the committee has policy statements on record.

Lyman J. Olsen, M.D.
Chairman

(The report was filed with approval of the recommendation that the committee have meetings on an ongoing basis.)

SPECIALTY SOCIETIES

Representatives of the specialties were invited to submit reports for inclusion in the House of Delegates handbook. The Medical Society of Delaware is interested in knowing about any special interests or concerns that come to the attention of the various specialty groups.

Peter R. Coggins, M.D.
Chairman

DELAWARE SOCIETY OF NUCLEAR MEDICINE

It has been an important year for the members of the Delaware Society of Nuclear Medicine. As hospital-based physicians, we have worked actively to make key public officials aware of our grave concerns over the Administration's Compromise Physician DRG Proposal. We wish to thank the Medical Society of Delaware for its work in this area and hope there will be continued action to create alternatives to such proposals in the future.

The creation of acceptable procedures for the disposal of low-level radioactive waste continues to be a national and local issue. Progress was made during this year towards the creation of an Appalachian Regional States' Compact for disposal of low-level radioactive waste by Delaware and our neighbors in Maryland, West Virginia, and Pennsylvania. Satisfactory procedures for handling waste products will require cooperative efforts between government, industry, and medicine. Achieving solutions will insure that radioisotopes will continue to be available for medical use.

H. Theodore Harcke, M.D.
President

(The report was filed.)

DELAWARE ACADEMY OF FAMILY PHYSICIANS

The Delaware Academy of Family Physicians has continued in its role of representing Delaware's family physicians in the national organization. Through our meetings and communications, we assist our members in taking advantage of the many services offered by the American Academy of Family Physicians.

Our fall and winter CME courses and our annual scientific meeting continue to provide our members with an opportunity to obtain informative, low-cost, local continuing education. By taking advantage of CME opportunities provided by the national organization and our local chapter, our members can obtain all of the credits necessary to meet AAFP requirements.

Beginning next year, the American Board of Family Practice and the American Board of Internal Medicine will jointly offer the opportunity for board certified family physicians and internists to obtain a Certificate of Added Qualification in Geriatrics. Those whose practice has included a substantial amount of geriatrics will have the opportunity to take a qualifying examination. Our local chapter is currently exploring ways to assist interested members in preparing for this examination through additional CME programs.

Lawrence M. Markman, M.D.
President

(The report was filed.)

DELAWARE PATHOLOGY SOCIETY

To sum up the year in Pathology regarding state and local events is to most succinctly quote from the College of American Pathologists, *CAP Today Newspaper*, 1:9, September, 1987: "With the work of two of the three committees with Medicare jurisdiction completed, the hard fought proposal to pay hospital based physicians through diagnosis related groups has succumbed for all practical purposes. The House Ways and Means Committee, July 29th deleted the proposal altogether, and the House Energy and Commerce Committee voted August 6th to prohibit implementation of DRGs for Radiologists, Anesthesiologists, and Pathologists. Energy and Commerce accepted a CAP negotiated

provision for a relative value scale, fee schedule for Pathology."

This was a victory indeed for not only hospital-based physicians, but probably helped offset a very serious precedent for all physicians. We as a Society would like to thank our State Society and the American Medical Association for their help during this crisis.

The other matter of interest to report is that the Delaware Pathology Society will participate in a multi-state conference committee in May 1988. We are included in the Eastern Regional Pathology Meeting Steering Committee and are working closely with the state of New Jersey. The meeting will take place in Atlantic City with the New Jersey, New York, Pennsylvania, Maryland and Delaware Pathology Societies participating.

Allan W. Levy, D.O.
President

(The report was filed.)

DELAWARE OCCUPATIONAL MEDICAL ASSOCIATION

The Delaware Occupational Medical Association held four meetings this year in the form of a dinner and a speaker. Subjects for this year have included: Epidemiology, the New Castle County Hazardous Materials' Advisory Council, the Occupational Physician's Role in Product Liability, and the Management of Drug Dependence in the Workplace. The May meeting was held jointly with the Delaware Occupational Health Nurses' Association.

The Association meetings are open to all interested physicians and nurses. Our Association and its members are involved in continuing efforts to address concerns about adverse effects of industrial processes and products on health and the environment. These should not be produced when appropriate industrial hygiene programs are in place.

William L. Sprout, M.D.
President

(The report was filed.)

DELAWARE PSYCHIATRIC SOCIETY

The Psychiatric Society of Delaware met in council on September 8, 1987. The Society has addressed many issues over the past year that have greatly affected the practice of psychiatry in Delaware. Two issues were selected by the Council that have been of the greatest concern to the practice of psychiatry in Delaware.

For the past several years, the Society has concerned itself with a lawsuit in which one of our members, a member of the Council, was judged by a jury to be guilty of negligence. The circumstances involved a patient that he treated at the Delaware State Hospital who, four and one half months after discharge, killed a member of the community in an automobile accident. The jury in its wisdom found him guilty of contributory negligence in that death. While there are many other issues that can not be discussed in the scope of this report, it remains

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that the courts in Delaware have decided that a psychiatrist, and perhaps any other physician, is directly responsible for the behaviors of his patient in future situations, at least into months afterward. While other jurisdictions have found that this position is untenable, the fact is that it is now law in Delaware. The Psychiatric Society, joined by the American Psychiatric Association and by the National Association of State Commissioners of Mental Health, has participated with the physician involved in an amicus curiae appeal to overturn this unfortunate decision. The issue at this point is the level of responsibility that has been treated by a physician in Delaware.

Of equal importance has been the discrimination against psychiatrists, who are practicing medical physicians in Delaware, by prepaid health plans. This discrimination has been found to exist both in the minds of administrators and physicians and has resulted in the bypassing of medical psychiatrists by members of the Medical Society of Delaware in favor of non-medical practitioners who do not hold medical licenses. The Psychiatric Society of Delaware has taken an activist position to identify those persons and organizations who are abetting this discrimination. It is taking public and private means to bring this case to our colleagues and to the public. The Society has taken the position that this must be changed and will be changed. The Psychiatric Society respectfully submits that the Medical Society of Delaware should investigate this situation and confront it for the good of the medical profession in general.

Harold Graff, M.D.
President

(The report was adopted.)

DELAWARE ASSOCIATION OF NEUROLOGICAL SURGEONS

In reference to the activities of the Delaware Association of Neurological Surgeons during the year of 1986-87, it is my pleasure to inform you that we had our regular business meeting on November 20, 1986, when the new officers were elected.

HMOs were mentioned as something that would influence the practice of neurosurgery, and it was suggested that every neurosurgeon should take individual action in this respect. One of the neurosurgeons mentioned that we should give our support to the HMO endorsed by the Medical Society as this would probably be the best chance for us to have our interests at heart rather than a third party. No general decision was taken in favor or against this subject.

Again, we discussed the meaning of second opinion. It was a general consensus that the second opinioner disqualifies himself for the surgery, and he should inform the patient through his secretary or himself that he is not available for the surgery. On the other hand, if the patient wants another doctor or another consultation and it is not a true second opinion, this should be stated beforehand so that the initial physician who sends him to the second opinioner will not lose his patient in an unwitting and unethical manner.

Our spring meeting took place on April 16th. Dr. Frederick Simeone gave the "Livio Olmedo Lecture." He spoke about spinal cord injury and after that we had a dinner where we shared neurosurgical information with our guest speaker.

It is my understanding that you are particularly interested in knowing about any special issues or concerns that have come to the attention of our specialty group. As you may know, neurosurgeons are in the worst situation regarding the malpractice crisis. In fact, many neurosurgeons have retired because they cannot afford this anymore. This is a very significant concern among us since we are getting to the limit where we are going to be able to afford the premiums that are imposed on us. We can no longer put the increase of the malpractice premium on the patient or the insurance companies since there has been significant freezing of our fees. It is not the availability of the malpractice insurance but rather being able to afford it that is becoming impossible. This is of a very serious concern among all the neurosurgeons in the country. It is our feeling that in less than five years many neurosurgeons, even in their early practice, will have to leave this field.

Another one of our concerns has been the abuse of helicopter transportation for medical emergencies. It is dangerous, and it does not significantly reduce the time of acute care. On the other hand, people have become more demanding in that respect and they want their relatives transported by helicopter even if they are not acutely sick. It is our understanding that at the present time it is the State which is paying for this transportation and it is being given free. Eventually the State will realize that this represents a significant expense and will give it to a private enterprise. This will increase the cost of the medical care, which is already high. Transportation by helicopter may not always be necessary but since the public is getting used to it, the insurance industry will have to start paying for it.

Otto R. Medinilla, M.D.
President

(The report was filed.)

DELAWARE CHAPTER, AMERICAN COLLEGE OF PHYSICIANS

In 1987, Dr. William Holloway was selected by the membership of the Delaware Chapter as president-elect. He will assume office in April 1988.

The scientific meeting for the 1987-88 fiscal year will be the annual Infectious Disease Symposium that Dr. Holloway is famous for. There could be other meetings as well.

The necessary legal documents to incorporate Delaware as an official legal chapter have been processed. The bylaws have been approved locally and in Philadelphia and are awaiting final action in Dover. Incorporation will finally give full legal force to a structure of officers, committees, and bylaws. The national organization of the American College of Physicians continues to work through its Washington, D.C., office as well as its Philadelphia office, to gain better recognition for internists and rewards commensurate with education, experience, and time committed to care of patients.

E. Wayne Martz, M.D.
Governor

(The report was filed.)

DELAWARE SOCIETY OF INTERNAL MEDICINE

In response to your request for input, I would like you to be aware of the following issues and concerns that have come to my attention.

I must say that I have been fortunate in that I have not been inundated with complaints. Whether this represents apathy or a true lack of problems, I do not know. MAACs have been a concern nationally. However, I personally have not experienced any major problems nor have any other internists or internal medicine subspecialty groups brought any problems to my attention.

However, a major concern is dealing with the various IPAs, HMOs and health plans that are now in existence in Delaware. Office staff are finding it increasingly more difficult to schedule patients' appointments and to schedule diagnostic studies and therapeutic procedures while trying to track down the patient's health policies. Frequently, patients calling for an appointment do not know what health policy they have. For example, they may know they have Blue Cross/Blue Shield, but they do not know whether it is Total Health Plus or HMO of Delaware or Pennsylvania Blue Cross, etc. Also, referral forms do not arrive in the physician's office with the patient or in a timely manner. This has caused increased work for office staff without proportionate financial reimbursement.

Susan K. Jonas, M.D.
President

(The report was filed.)

AMERICAN COLLEGE OF SURGEONS, DELAWARE CHAPTER

I am writing to give you the annual report of the American College of Surgeons.

At the present time we do not have any special problems. General problems pertaining to medicine as a whole are already known by the state medical society.

Mustafa Oz, M.D.
President

(The report was filed.)

DELAWARE ACADEMY OF DERMATOLOGY

As president of the Delaware Academy of Dermatology, I have been asked to convey our feelings about certain issues that confront our specialty.

As a group and as individuals, we dermatologists are deeply concerned about the increasing incidence of skin cancer in our population and the many factors that are contributing to this problem. There is considerable debate concerning the question about whether the physical atmosphere is allowing more ultraviolet light to reach the surface of the earth. While scientists are debating this theoretical problem, we have to deal with the fact that American lifestyles have changed within the past 40 years and the average American has considerably more leisure time to pursue interests in direct sunlight. Improved transportation and increased discretionary income have provided more opportunity

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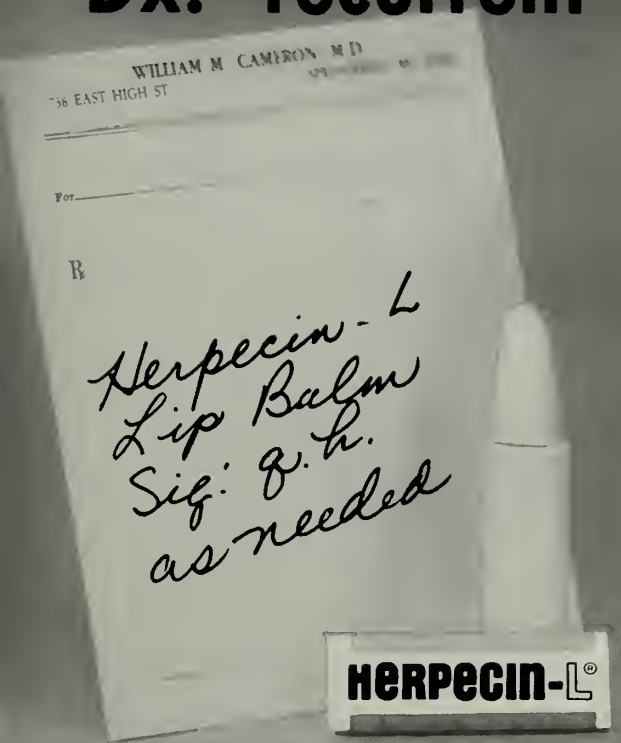

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for people to enjoy themselves in the sun, at the beaches, and in their own backyards. In addition, more Americans have found the resources to travel periodically to southern climates for recreation and retirement. We are certain that changed lifestyles are a great contributing factor to the increase in skin cancer.

We face on a daily basis innumerable patients in our offices and have been attempting to educate them about the perils of sunlight and its central role in producing skin cancer. However, these are people who have come to us with a perceived problem. The great majority of people have to be informed through the public media about the dangers of the sun. Our Society participated in June, 1986, in the KYW Health Fair held at Concord Mall where individual dermatologists manned a booth, examined over 300 individuals, and distributed both sunscreens and literature. Many of these people had extreme sun damage, and some had previously unrecognized skin cancers.

Recent publicity concerning President Reagan's sunlight-induced basal cell carcinomas has helped us to publicize the intensity of the problem. We are hopeful that the Medical Society in cooperation with our organization will be receptive to future expenditures of time, money, and energy in helping to prevent skin cancer.

Richard H. Bonder, M.D.
President

(The report was filed.)

AMERICAN ACADEMY OF PEDIATRICS, DELAWARE CHAPTER

In answer to your request for information on special issues tha affect our specialty, I respectfully submit the following concerns:

Infant Mortality. Although the Legislative Task Force on Infant Mortality was established a few years ago and is meeting under the able direction of Dr. Lyman Olsen, statistics still show room for improvement. It is appalling that in the U.S. the infant mortality rate is 10.6 per thousand live-births and ranks 18th among developed nations (Japan, 6.0; Finland, 6.5; Sweden, 6.7). Delaware, by 1990, has been projected to have one of the highest rates in the U.S. if this situation is not corrected. Hopefully, the Legislative Task Force will coordinate its effort with urgently needed adolescent pregnancy initiatives and with the Maternal and Child Care Committee of the Medical Society of Delaware to correct the course of a situation that needs urgent attention.

Catastrophic Health Insurance Coverage for Children. One of the goals of the American Academy of Pediatrics has been the elimination of financial barriers that could interfere with access to quality health care for children. The cost of catastrophic medical care could eventually become a barrier. This is a very important and critical matter that we should be dealing with at both national and state levels. Fortunately, this issue has found sympathetic ears in Washington, D.C., where there has even been interest expressed in including coverage for chronically ill children. We pediatricians are also concerned with the increasing number of families that are dropping out from traditional health insurance coverage just because they cannot afford it. We see this crisis as potentially explosive and we think something should be done soon to defuse it.

Vaccine Compensation. The Delaware Chapter of the American Academy of Pediatrics applauded President Reagan when he signed the Accident Vaccine Compensation Bill. But until the Ways and Means Committee of Congress finds funding for such a bill, the cost of vaccines will not significantly decrease and the liability of physicians administering them will remain in jeopardy.

AIDS. We strongly urge the Medical Society of Delaware to initiate an active education campaign to include its own members and the public. Unless the medical profession can convince itself of the limited epidemiology of AIDS, we will not be able to restrain public hysteria. This subject also contains particular medical, ethical, and legal questions which we should be addressing before we hear the thunder.

Maurice Liebesman, M.D.
President

(The report was adopted.)

REPORT OF THE NOMINATING COMMITTEE

A meeting of the Nominating Committee was held at the Delaware Academy of Medicine Building in Wilmington on October 13, 1987, to consider positions to be filled for the year November 1987 through November 1988.

Martin J. Cosgrove, President-Elect, 1986-87, will assume the office of President.

Henri F. Wendel, M.D., Vice President, 1986-87, will assume the office of President-Elect.

The following nominations were made:

Vice-President	- Ben C. Corballis, M.D.
Secretary	- Harry M. Freedman, M.D.
Treasurer	- Ali Z. Hameli, M.D.
Representative to the Delaware Academy of Medicine	- Leonard P. Lang, M.D.

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REPORTS OF LIAISONS AND REPRESENTATIVES

AMERICAN CANCER SOCIETY, DELAWARE DIVISION

The Delaware Division of the American Cancer Society has found the year 1986-87 to be one of both progress and transition.

This past year, the Society served 1,088 patients, an increase of 200 over the number of patients served during the previous fiscal year. This does not mean we have been able to provide all the services for all the patients requesting them. Only a greater volunteer involvement and increased funding will allow that to occur.

The Delaware Division sponsored a statewide Breast Cancer Detection Awareness Program which was held in all the acute care hospitals as well as some free-standing radiology clinics in the spring of 1987. This was successful, but it is the concern of the Society that the medically and financially indigent in the inner city are not being reached. With the follow-up program in the coming year, we are hoping to take the program out of the hospitals and into local churches and/or community centers to reach more people.

Transition has occurred with the hiring of a new Executive Vice President, Dr. Patricia Patten-Seward, who comes to Delaware from upstate New York with a strong background in managing volunteer organizations. We are looking forward to continued progress and expansion under her expert management and guidance.

It again must be noted that only 43 physicians and dentists throughout the entire state are involved with the American Cancer Society. Further involvement of a

greater number of our physicians would markedly improve the services which can be provided by your American Cancer Society.

Charles A. Depfer, D.O.
Liaison

(The report was filed.)

AMERICAN DIABETES ASSOCIATION, DELAWARE AFFILIATE

The Delaware Affiliate, Inc., of the American Diabetes Association has been serving the people of Delaware since 1948. Working through Chapters located in each county, the Affiliate conducts a balanced program of education, detection, and fund raising to support research for a cure or preventative for the disease.

Programs and services include:

- Diabetes management classes
- Diet management classes
- Summer day camp for youth grades 1 through 12
- Youth leadership club
- Adult support group
- Family support group
- Scholarship program for children to attend summer resident camp
- Monthly Chapter meetings
- Health fairs and public meetings
- Professional education programs for physicians and other health care professionals
- Free diabetes screening programs
- Information and referral program
- Monthly newsletter
- Speakers' bureau
- Displays in various malls and other public gathering places

Grafton D. Reeves, M.D.
Liaison

(The report was filed.)

AMERICAN HEART ASSOCIATION OF DELAWARE, INC.

The role of community programs is to concentrate effort and available resources to program delivery where the majority of health interventions will impact a majority of the population. This year, through American Heart Association programs, we had nearly 102,000 contacts with Delawareans from ages four to 74. Our programs reached children in schools, employees at worksites, cardiac patients in hospitals and other people at senior centers, supermarkets, and at local health fairs. Over 110,000 free American Heart Association pamphlets answering every conceivable question on cardiovascular health were distributed upon request or through physicians' offices. The following programs would not have been possible without the hundreds of volunteers who unselfishly gave of their time to care about the hearts of others.

Research. Research is the first order of business of the American Heart Association. In 1987, $136,000 was expended in grant-in-aid and fellowship support to nine research investigators by the AHA of Delaware.

Emergency Cardiac Care. The National Conference on Standards and Guidelines for CPR in July 1985 yielded new and revised recommendations regarding the teaching and performance of basic and advanced life support. Statewide update sessions were scheduled beginning in July 1986; 571 Basic Life Support and 115 Advanced Life Support instructors were certified according to the new standards. A total of 1,629 CPR courses were conducted by volunteer instructors training 14,190 persons in this life saving technique. In addition, 157 persons learned CPR through the aid of computers at the Association's offices. Statewide training in Advanced Life Support is now in its fifth year. Twenty-five ACLS Provider courses were conducted at six hospitals, training 470 medical professionals to administer advanced life support. To maintain a faculty to teach these courses, Heart annually conducts one ACLS Instructor course. This year, 34 medical professionals were trained as ACLS Instructors, which brings the number of ACLS Faculty in the state to 137.

Professional Education. Medical and related health professionals are regularly provided with updated information on cardiovascular issues as they relate to research, patient care and other specialized areas. Over 22,000 copies of medical newsletters, including *Modern Concepts, Cardiovascular Nursing, Stroke*, and *Cardiovascular Research Report* were mailed to physicians and nurses this year.

Community Services. As a community service, Heart volunteers conducted free blood pressure screenings regularly throughout the state. This year 85 screenings were conducted with 3,518 persons screened. Heart's Speakers' Bureau provides another forum for dispensing Heart information to the general public. An estimated 1,140 persons listened to Heart volunteers advocating heart health at 29 programs in the past year and AHA literature was disseminated at 21 health fairs throughout the state. Financial support is also provided to Tel-Med, a service of the Academy of Medicine. Approximately 600 calls are recorded per month requesting information on cardiovascular disease. Heart's film library consists of nearly 50 professionally produced films and are available for loan to schools and industry upon request.

Diet and Nutrition. Diet and Nutrition programs are expanding and reaching people in several ways. AHA's second annual Food Festival was conducted in 46 supermarkets throughout the state. This week-long awareness program helped the consumer choose foods that are lower in cholesterol and fat. Over 62,000 educational brochures were distributed to customers. Registered dietitians set up tables displaying heart healthy foods and were available to answer questions. A videotape produced by AHA of Delaware played continuously in 13 stores. The "Heart Healthy Dining In Delaware Guide" was completed this year. Forty-five restaurants are listed along with suggestions for heart healthy food selections. Culinary Hearts Kitchen takes a positive approach to nutrition by teaching individuals what they can do, can eat and can add to their diet in order to maintain a nutritionally sound lifestyle. An orientation to this course was offered to Registered Dietitians and Home Economists to introduce them to AHA dietary recommendations and the Culinary Hearts course.

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Cardiac Rehabilitation. AHA's services in cardiac rehabilitation involve education and support for hospitalized patients and persons in the community affected by heart disease. Nine hospitals in Delaware now provide bedside education to cardiac patients using videotapes, slides and other educational materials funded by the American Heart Association and Heart Ball proceeds. The hospitals offering cardiac patient programs are Beebe, Milford, Christiana, Wilmington, Kent General, Veterans Administration, St. Francis, Riverside and Nanticoke. A chapter of the Mended Hearts was organized in July 1986. This support group, for persons who have experienced cardiac surgery, meets monthly. The primary function of Mended Hearts volunteers is to visit patients and their families to provide support during and after cardiac surgery. In addition, cardiac support groups for post m-i patients meet regularly in Kent and Sussex counties.

School Programs. The Heart Treasure Chest is a program designed to teach three to five year old children about the heart and heart healthy lifestyle habits. AHA, in cooperation with the Department of Public Instruction, offered a teacher orientation session to non-profit preschools throughout the state. In attendance were 48 teachers representing 33 preschools. Each school represented received a free Heart Treasure Chest. The Tin Man visited students in Kindergarten through 2nd grade in an effort to teach them about the heart and how to keep it healthy. This assembly program was presented to 17,831 students in 83 public, private and parochial schools in Delaware. For students in grades 8-12, our programs stressed the importance of not smoking. Save a Sweetheart, an anti-smoking program, encouraged students to quit smoking on Valentine's Day. Non-smokers signed pledge cards indicating that they would not start smoking for one year. In all, 2,161 students in 15 schools participated.

Worksite. Our worksite program, Heart At Work, has been designed to help employees to develop positive lifestyles by controlling high blood pressure, smoking, following a heart-healthy diet and engaging in regular physical activities. In conjunction with this program and prior to its implementation, employees participate in a health risk survey. To date, four companies in Wilmington are involved in our worksite program.

On behalf of the American Heart Association of Delaware, I wish to thank the medical community for their continuing support of the Association and its many varied programs.

Michael E. Stillabower, M.D.
Liaison

(The report was filed.)

AMERICAN LUNG ASSOCIATION OF DELAWARE

The American Lung Association of Delaware has spent 1986-87 working towards its number one priority of a Smoke-Free Family. This priority is designed to help the Surgeon General meet the goal of a Smoke-Free Society by the year 2000.

Smoking education was an integral component of working towards a Smoke-Free Family. The Lung Association continued to provide materials, curriculums and workshops for public, parochial and private schools

throughout the state. This year 1,100 elementary school students heard information on the harmful effects of cigarette smoking. Three hundred and fifty school personnel attended various workshops on smoking, stress management and lung health.

Free materials were provided statewide. Health curriculum such as Marijuana: A Second Look; Smoking Deserves A Smart Answer; and Lungs Are for Life modules were distributed. The Biofeedback Smoking Education Program, which utilizes four pieces of equipment to help students learn about the immediate physiological effects of cigarette smoke, was utilized 18 times during the school year. A curriculum on smokeless tobacco was developed. The curriculum was used for Just Say No Day. A project was piloted with the Brandywine High School DECA students. The pilot project encouraged the high school students to use specific American Lung Association programs and teach elementary/ junior high students about the health hazards of smoking.

Another integral component of the Smoke-Free Family was smoking cessation in the community and in the workplace. Over 800 individuals have utilized the Freedom From Smoking programs. The programs included one of three approaches: self-help, clinic and videocassette. A monthly support group was held for individuals who needed additional support to maintain their nonsmoking status. This year a "Delaware Nonsmoker's Guide" was published. The guide informs individuals of 31 establishments throughout the state which provide nonsmoking sections. Approximately 500 guides were distributed.

The Delaware Coalition on Smoking OR Health continued to work on "No Smoking in Certain Public Places" legislation. Two public hearings were held on the bill, one in Wilmington and one in Dover. Testimony was given by the American Lung Association of Delaware. The bill was passed in the House and is now awaiting a vote in the Senate.

In the area of adult lung disease, a Better Breathing Support Group met monthly. Various topics were covered. One hundred thirty participants used this service. "Help For The Patient With Lung Disease" programs were held in New Castle and Kent Counties. The Adult Lung Disease Resource Directory was updated with grant monies from Happy Harry's Home Health Care. A bi-monthly newsletter was distributed to 250 individuals.

A new program on Influenza was implemented. Over 1,200 packets were distributed to physicians, long-term care facility medical directors, and long-term care facilities. A grant from the DuPont Company enabled the purchase and distribution of these materials.

Several programs were held in the area of Pediatric Lung Disease. Thirty-three families attended the Preschool Asthma Programs and the Family Asthma Programs. Approximately 800 families now receive the bi-monthly newsletter.

The Parent Monitoring Association, which is for parents with children on apnea monitors, continued to meet monthly. A quarterly newsletter, *The Monitor*, was added to this program area.

Pediatric Health Issues Workshops for Daycare and Preschool Providers continued to be held statewide. Topic areas covered included: infant apnea/home monitoring, childhood asthma, curriculum for the prevention of choking and pediatric CPR training certificate.

Daily air quality reports and weekly pollen counts were provided to local newspapers and radio stations. Presentations on indoor and outdoor air pollution continued.

Support of six medical journals, 11 Tel-Med tapes and various scholarships continued. The Lung Association also remained active in providing community services such as pulmonary function screening, carbon monoxide testing and health fairs.

As indicated above, the American Lung Association of Delaware has many accomplishments to be proud of in 1986-87. To accomplish these things, we need dedication from many people. We extend our thanks to the individuals of the medical community who volunteer their time and effort to work with us.

Leonard P. Lang, M.D.
Liaison

(The report was filed with approval of the recommendation that the Medical Society of Delaware should restate its official standing regarding the goal of a "smoke free" society by the year 2000.)

CONTROLLED SUBSTANCES ACT ADVISORY COMMITTEE, STATE OF DELAWARE

Delaware physicians beware: Pennsylvania has put in a drug control regulation that bans the use of amphetamines and imposes a combined 45 days per year allowable prescription on all other anorectics for weight control. This regulation has already caused unusual sale of anorectics from some physicians' offices in Delaware; no prescriptions are necessary. Delaware will try to get legislation similar to Pennsylvania in order to curtail this unusual practice pattern.

Forgeries are appearing with the physician's legal signature. The forgery is of the tally of numbers and refills. The forger sees the number 10 and changes it to 40 or 100; at the same time he notes the refills can be changed from one to five or even prn. If numbers are accompanied by the written word, it could block the forger in both instances.

The past year started with the announcement of the following amendments to the Controlled Substances Act:

1. Registration will henceforth be biennial.
2. It is a felony to use another person's registration.
3. It is a crime to make or manufacture a non-controlled substance, i.e., steroids.

Reported to the Committee were diversions from nursing homes and hospital by their personnel.

The D.E.A. has been urged to make a change in authorized refills allowed; the attitude is that fewer refills means more control and better medicine.

Cocaine is still the most-used street drug in many forms, but the controlled drugs are almost equally a problem. The use of methylphenidate since 1982 is up 36%, codeine is up 5%, hydrocodone is up 121%, oxycodone up 29%, hydromorphone up 19%, and methadone up 69%.

The Medical Advisory Committee on Controlled Substances had three meetings during which the above material was discussed. The Advisory Committee is composed of Lyman J. Olsen, M.D., Director of the Division of Public Health, Chairman; Martin Golden, Director of Drug Control and Abuse, Secretary; Ali Z. Hameli, M.D., State Medical Examiner; Captain John Perry, representing the State Police; Rhoslyn J. Bishoff, M.D., representing the Medical Society; Jane Taylor, R.N., representing the State Nurses' Society; and David Lyons, representing the Attorney General's office.

Rhoslyn J. Bishoff, M.D.
Representative

(The report was filed with approval of the recommendation that the Board of Trustees encourage the development of regulations concerning amphetamine use to conform to those in the surrounding states, and that the Board look into the potential Drug Enforcement Agency restrictions on allowable refills as a further intrusion on the autonomy of physicians.)

COORDINATING COUNCIL FOR THE HANDICAPPED CHILD OF DELAWARE, INC.

The Coordinating Council sponsors two public meetings during the year. The 1986 Fall Conference highlighted the topic "Delaware's Small Wonders--Normal Development and Warning Signs of Problems in Young Children." This conference was held in conjunction with the Division of Public Health and "Focus on the First Sixty Months." Over 230 people attended, representing agencies in health, social services, day care, early childhood education, and child welfare. This conference highlighted the need for increased training for daycare providers and availability of day care for handicapped children. The Coordinating Council is continuing to work on the coordination of day care programs for special needs children.

The second large meeting was held in May, 1987, in order to provide information about the impact of the new education law (P.L. 99-457) on early intervention programs and services for handicapped infants and toddlers. The Coordinating Council responded to the need to understand and plan for the implementation of this new law in a collaborative and positive way. During the spring meeting, Dr. Henry H. Stroud was awarded the Alfred R. Shands, Jr., M.D., Distinguished Service Award. Dr. Stroud was recognized for his outstanding leadership in the field of developmental pediatrics and for his commitment in the provision of services to Delaware's children and their families.

In addition, the Coordinating Council planned two seminars this past year which were presented at The Medical Center of Delaware's Pediatric Grand Rounds. The topics included:

— Child Mental Health Services in Delaware and the Primary Mental Health Prevention Model.

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The goal of these seminars is to orient pediatricians to available community resources.

The Coordinating Council is involved with two special projects. The Statewide Health Careers Internship Project continues to offer high school students the opportunity to explore a career interest in the health area at Delaware's prominent hospitals and other health facilities while earning credit as a volunteer intern. The Specialized Babysitting program trained 11 babysitters with Red Cross certification to babysit for special needs children. Babysitters are listed with United Way of Delaware's First Call for Help (656-4630).

The Coordinating Council continues to serve as a forum to promote inter-agency projects and advocacy efforts for Delaware's handicapped children. During the past year, the Council provided professional assistance to:

- Advisory Committee to the Governor's Early Childhood Project — "Focus on the First Sixty Months."
- Developmental Disabilities Case Management Committee.
- Department of Health and Social Services' Long Term Care Task Force on Finance and Management.

Lyman J. Olsen, M.D., M.P.H.
Liaison

(The report was filed.)

DELAWARE CHAPTER ARTHRITIS FOUNDATION

The Arthritis Foundation was active in the Delaware community during 1987 in several ways. Commitment to continuing medical and lay education was demonstrated by the 1987 Rheumatology Update, with plans for another program in 1988. Patient support groups, self-help courses, and in-water exercise classes continued and have been very popular. The Foundation maintains a library of information materials that is available to the general public. Through the Medical and Scientific Committee, continuing programs are evaluated to enhance the welfare of arthritis patients in Delaware.

James H. Newman, M.D.
Liason

(The report was filed.)

DELAWARE EPILEPSY ASSOCIATION

The Delaware Epilepsy Association continues to carry out its mission of educating the public as to the nature of epilepsy and how it affects the psychosocial well-being of the people affected by this condition and their families. In doing this, between August 31, 1986, and September 1, 1987, the Delaware Epilepsy Association has presented 11 school alert programs and 11 public awareness/inservice training programs and attended one national conference, where one of our professional advisory speakers presented information on family therapy. Seven hundred phone calls were received from Tel-Med. There were three newspaper articles, three Health Fairs, and one radio talk show, and two newsletters have been started by self-help groups. One of the more exciting features that has occurred is the development of self-help groups in all three counties that have been meeting to help support those with these difficult problems, and in addition, have been spreading newsletters and brochures that have reached over 4,000 people.

We continue to ask the Society and physicians in the State of Delaware to support efforts to make the lives of people with epilepsy more comfortable.

One particular area on which we are still working and will be contacting the Medical Society is an attempt to rewrite the motor vehicle laws to more properly reflect modern thinking in regard to epilepsy and driving in this state.

S. Charles Bean, M.D.
Liaison

(The report was filed.)

DELAWARE INSTITUTE OF MEDICAL EDUCATION AND RESEARCH (DIMER)

DIMER continues to carry out its role of facilitating the admission to Jefferson Medical College of Delaware residents who seek a career as a physician. The State of Delaware has appropriated funds which in recent years have been allocated by the DIMER Board as follows:

	1984-85	1985-86	1986-87	1987-88
Jefferson Medical College	$1,119,960	$1,175,960	$1,200,000	$1,200,000
Jefferson for Delaware				32,500
Student Research Scholarships	150,000	157,500	199,000	223,200
Del. Academy of Medicine	1,000	1,000	1,000	1,000
University of Delaware	43,344	45,494	47,700	49,000
Medical Center of Delaware	174,096	185,046	194,300	203,000
	$1,488,400	$1,565,000	$1,642,000	$1,708,700

In May 1987, 20 Delaware residents received the M.D. degree from Jefferson. The past year 37 Delawareans applied for admission to Jefferson. Of these, 18 were offered acceptances and in September, 12 matriculated.

Tuition at Jefferson this year is $15,260, and the estimated average cost of a year at Jefferson is now $25,000. In an effort to counteract the deterrent effect of this high cost, the DIMER Board has made major increases in the allocation to scholarships in recent years. They have now also earmarked some Jefferson funds for research to be done by Delaware students, in an effort to attract those Delaware students with an interest in this area.

E. Wayne Martz, M.D.
Liaison

(The report was filed.)

DELAWARE POLITICAL ACTION COMMITTEE (DELPAC)

DELPAC's activities during the past year, an "off election year," were chiefly confined to lobbying efforts on behalf of organized medicine both on a national and statewide level. These activities included further development of the key contact program organized by Dr. Brett

Eliott, with the able assistance of Mrs. Jacqueline Alvarez.

Dr. Elliot's and Mrs. Alvarez's intense lobbying efforts of our Congressional delegation on the Senate and House Concurrent Resolutions were most effective.

Success in lobbying support for these resolutions, which strongly opposed physician DRGs and other possible Medicare reimbursement changes, can be directly attributed to the efforts extended by these two exemplars of what can be accomplished with ingenuity, persistence, and friendliness.

The 1987 season began with AMPAC generously sponsoring and funding a dinner at the Du Pont Country Club in an effort to increase political awareness among physicians in this state. The featured speaker was Congressman "Sonny" Montgomery, a member of the Armed Services and Veterans Affairs Committee, who was introduced by Congressman Tom Carper. The dinner was exceptionally well attended and was instrumental in maintaining and increasing our DELPAC membership penetration in the state society.

During the past year, DELPAC has supported additional fundraisers for state and federal candidates. Representatives both from the Board and from the general membership attended and met with the candidates and made the concerns of the medical community known.

In the upcoming election year, the Board has developed an ambitious program of breakfast meetings with key congressional and state representatives and members of the Society. They are also planning another congressional and gubernatorial debate similar to the extremely successful one held during the last presidential campaign.

DELPAC is the only bipartisan political voice of the Medical Society of Delaware. Through its efforts, our positions on quality health care legislation are presented to political representatives both in Dover and Washington who daily decide on bills that affect the manner in which the practice of medicine is performed. Your Board of Directors has as its only interest supporting electable candidates who will listen to our positions and share our interests in the delivery of quality health care.

Contributions to DELPAC made on personal checks are divided 50% to DELPAC and 50% to AMPAC; made on corporate checks, all the funds go to DELPAC for candidate support in Delaware.

New Castle, Kent, and Sussex Counties share bipartisan representation on the DELPAC Board and there are members representing each of the hospitals in the state. The 1987 Board of DELPAC is comprised of the following: Daniel A. Alvarez, M.D., Mrs. Daniel Alvarez, Gustave K. Berger, M.D., Leroy Buckler, M.D., Jeffrey L. Chait, M.D., I. Favel Chavin, M.D., Peter R. Coggins, M.D., Ben C. Corballis, M.D., Martin J. Cosgrove, M.D., Steven Edell, D.O., Brett Elliott, M.D., John F. Gehret, M.D., Robert E. Heckman, M.D., Joseph F. Kestner, Jr., M.D., Lazarus M. Kirifides, D.O., Vincent G.J. Lobo, D.O., Mrs. David Medland, Jorge A. Pereira-Ogan, M.D., Anis Saliba, M.D., Marguerite D. Thew, M.D., and Ignatius J. Tikellis, M.D.

The Auxiliary of the Medical Society of Delaware has been extremely helpful through its efforts in assisting in individual lobbying efforts on specific issues. This support is gratefully acknowledged.

Again, we would like to reiterate to the members of the House of Delegates that increased membership proves our effectiveness as a political voice. The states which have the greatest percentage of AMPAC members are those where malpractice and other issues are severely threatening the manner in which medicine is practiced. By increasing our political influence on medical matters at this time, we can avert the type of problems that are being experienced in Florida and other states at the present time.

Peter R. Coggins, M.D.
Chairman

(The report was filed.)

LEGISLATIVE REPORT

The legislative sessions of non-election years do not terminate but carry into the following year. Thus, all legislation introduced but not passed in 1987 will remain on the table for consideration in 1988 unless it was actually defeated on the floor.

Many such bills of importance to the Medical Society fall into that category. Among them:

HB 4 - Measure to prohibit smoking in certain public places.
Passed House and out of Senate Committee, but no Senate vote as yet.

HB 5 - Establishing safe boating regulations for both the vessel and the operator.
Passed the House and out of committee in the Senate but no vote on the floor.

HB 44- Licensure of Nutritionists.
Passed House, still in Senate Sunset Committee.

HB147- Prohibiting the operation of a boat while under the influence of alcohol.
Passed House, still in Senate Committee.

SB 44- To provide statewide paramedic services.
Passed Senate, but in House Human Resources Committee.

All of these bills should come up when the General Assembly reconvenes on the second Tuesday of January, 1988.

Also still possible for future re-consideration, though defeated in 1987, are the seat belt bill, HB 80, requiring their use in Delaware, and HB 10, req
uiring the posting of signs to warn pregnant women of the danger of alcohol. The seat belt bill passed the House but was defeated in the Senate, where it can be restored during the next two legislative days. The pregnant women warning bill failed after lengthy debate in the House but can also be restored in January.

The Medical Society will also be watching the series of tort reform bills that remain pending. One, to change the policy on claims in respect to the joint and several liability, was debated on the House floor but shelved by its proponents after adoption of a crippling amendment requiring a study before implementation.

There is also a bill in the Senate, introduced by Senator McDowell, which would repeal the medical malpractice act in its entirety. SB 144 is in committee and has been since its introduction May 12th.

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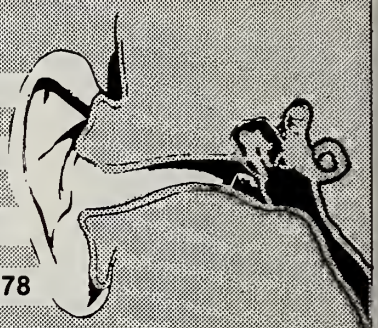

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Among the bills of interest that passed in 1987 were HB 18, giving the Board of Medical Practice the authority to temporarily suspend licenses if necessary pending the results of a formal hearing; HB 56, authorizing licensing of counselors, which was a compromise worked out with psychologists; HB 102, providing people enrolled in dental plans with certain "freedom of choice" options in dealing with their insuror; and SB 28, which provides exemptions from civil liability for individuals rendering emergency care under certain circumstances.

Ned Davis
Legislative Specialist

(The report was filed with approval of the recommendation that the Society continuously reassess its position on tort reform and consider a balanced package of legislation on peer review and tort reform.)

MARCH OF DIMES BIRTH DEFECTS FOUNDATION

During the past year, the chapter has been actively involved with a Legislative Task Force on Infant Mortality and the Southern Governors' Association Regional Task Force on Infant Mortality. Both of these task forces are in the forefront of efforts to reduce the terribly high incidence of infant mortality, both here in Delaware and throughout the south. The March of Dimes has been a prime source of information and funding for these efforts. The chapter also funded several local grants which we are confident will result in healthier infants:

1. $1,000 was awarded as start-up money for the new Perinatal Association of Delaware.
2. $2,000 was granted to the local chapter of Alpha Phi Alpha fraternity to sponsor a one-day seminar for preteen and early teen males. The seminar targeted the problems inherent in adolescent pregnancy and the male's role in that problem.
3. $2,500 was awarded to the New Horizons Teen Theater in Cecil County, Maryland. This group of teenage students travels throughout the area presenting skits and plays to their peers, also dealing with the teen pregnancy problem.
4. $5,000 was approved to be used for another "Genetics Week" for professionals, scheduled for next spring. The tremendous success of the first genetics week in 1986 was directly responsible for our decision to sponsor another program.
5. $900 was awarded to the EPIC Program, which stands for "Effective Pregnancy & Infant Care." Our funds were used to purchase materials which are distributed to women with high-risk pregnancies.
6. $750 was awarded to the Delaware Parents of Downs, a parent support group. Other appropriations include: Premies of Northern Delaware, another parent support group, as well as Tel-Med tapes dealing with healthy childbearing.

Individual committee members have been involved as speakers for the "Good Health Is Good Business" program. This in-company health education program brings our message to the workplace where the number of women of childbearing age is at an all time high. The chapter also distributed record numbers of free materials and audio-visuals to schools, clubs, doctors' offices, clinics, and the general public throughout the year. In addition, approximately $140,000 was contributed to March of Dimes research funded projects.

In conclusion, the March of Dimes is dedicated to continuing to assist health professionals in ancillary related services involved in the care of children at risk for birth defects.

Michael L. Spear, M.D.
Liaison

(The report was filed.)

MEDICAL ADVISORY COMMITTEE, DIVISION OF ECONOMIC SERVICES, STATE OF DELAWARE

The Medical Advisory Committee to the State of Delaware, Division of Economic Services, met once during the past year. Mrs. Phyllis Hazel, DES Director, was our guest speaker and made a presentation on a study conducted by James Bell Associates entitled "Gaining Ground; Public Assistance Program Redesign in Delaware." There were comprehensive findings on the welfare population and system in Delaware including:

1. Number of dollars spent on programs such as AFDC, Food Stamps, Medicaid, Employment and Training, Emergency Assistance, etc.
2. Comparison of payment standards for AFDC with the nation and surrounding states.
3. Percentage of payment standards compared to the poverty level.
4. Length of time Delaware recipients remain on public assistance.
5. Comparison of benefits between a public assistance recipient and a minimum wage earner.

Ad Hoc committees formed for research and to make recommendations on some of the major findings of the study in areas of employment and training, and indigent health care coverage were discussed. Recent federal regulation was discussed which allows Medicaid an option to cover pregnant women and children up to 100% of poverty level, and this option has been put in the Division's 1988 budget request.

The Psychiatric Society of Delaware has stressed that we look particularly at psychiatric coverage. This along with new alternative modes of health care coverage will be our focus in the coming year.

Patricia H. Purcell, M.D.
Liaison

(The report was filed.)

THE MEDICAL SOCIETY OF DELAWARE AUXILIARY

The Auxiliary of the Medical Society of Delaware faces an active, challenging, transitional, and rewarding year. We now have a membership of approximately 400 members statewide. Our organization is experiencing a coalition effort of time, talent, and dedication within our ranks.

Successful programs already instituted remain in effect. A few examples include the Infant Hearing Assessment Project, continued commitment to fund-raising activities for scholarships, and support of community service organizations.

Some of the highlights of county activities this past year in New Castle County included obtaining a $10,000 grant from the Crystal Foundation, through the effort of Mrs. Robert Frelick, to benefit the Infant Hearing

Assessment Program. The Auxiliary supplemented this further with a $3,500 donation raised at their fall fashion show. Placenta Bears were also purchased for the newborn nursery at Christiana Hospital. Auxilians were active participants in the Family Fun Day at A.I. du Pont Institute and held a wine and cheese reception featuring special edition prints by Dr. Bill Renzulli. A contribution was also made to the Marchese Clinic in Zambia, Africa, in response to a request for assistance. A Christmas party for the children of New Castle County medical families was organized and will be repeated this holiday season. 1,000 copies of "Threads of Greatness" books were presented to Governor Mike Castle for distribution to Delaware school children.

A membership brunch featuring New Castle's own Sherlock Holmes look-alike was held at the end of September and this year's fashion show is to benefit Child, Inc.

In the Spring of 1987, Kent County Auxilians awarded a $2,000 health career scholarship to a graduating student. The first annual Harvest Ball took place in September, and a social get together for new auxiliary members is planned. Spring activities are still being organized here as in other counties.

Sussex County Auxilians continue their support of the Beebe Hospital School of Nursing and the Francis Baylis Education Loan Fund, donating the $3,000 proceeds from their fall fashion show. Members worked in conjunction with the American Cancer Society to help raise $2,500 through the Daffodil Sale and also made a $450 Auxiliary contribution. Delaware Hospice received support as well as a program aiding migrant workers and a nursing student from Sussex County. The "Recipe Auction" fundraiser is an annual event.

Our transitional phase concerns programs involving all counties addressing uniform objectives. The Auxiliary is very concerned about the well-being of the adolescent. We plant to work this year to increase state-wide awareness of areas of adolescent health problems detailed in the AMA "White Paper on Adolescent Health." The Auxiliary was one of the co-sponsors of the Adolescent Suicide program presented in October, and each county has been encouraged to plan local involvement in the overall initiative.

"Meet Your Local Legislators" informal receptions have been suggested in all three counties. Each county is also coordinating a sale of official Medical Society of Delaware ties for physicians as a state-wide AMA-ERF project.

On the state level, four Auxilians attended the AMA Auxiliary Annual House of Delegates meeting in Chicago. The Auxiliary actively participated in the "Great American Buckle-Up" in support of passage of a state seat belt law. Auxilians traveled to Washington, D.C., to meet with Senator Roth and Congressman Carper to discuss RAP—DRGS, and one of our Auxilians, Mrs. Daniel Alvarez, was especially successful in her contact with Congressman Carper soliciting his support for this matter. Two of our members attended the regional conference on AIDS. The Auxiliary will participate in two Leadership Confluences this year and, as state president, I will attend the regional White House Conference for a "Drug-Free America."

We appreciate the opportunity to voice our support for the now-mandatory health education policy for Delaware school children in K-12 advocated by the Medical Society. The Auxiliary also wants to thank the Medical Society of Delaware for the opportunity to attend your Board of Trustees' meetings and standing and special committee meetings as invited guests. You provide us with the means to become better informed. A special thanks to Dr. Alvarez for his continued interest and support as the liaison from the Medical Society to the Auxiliary. I especially want to thank Dr. Peter Coggins, MSD President, for the invitation to present this report.

Mrs. V. J. Maximo
President

(The report was filed with commendation to the members of the auxiliary on their excellent work.)

MEDICAL SOCIETY OF DELAWARE INSURANCE SERVICES, INC.

During this past year, MSDIS has done generally well. We have affiliated with the Jefferson-Pilot Corporation as a general agent for the sale of insurance. This affiliation allows us to market life and disabililty insurance. And, we could also offer financial and estate planning. As of this time, our membership has shown no interest in the products we are able to offer them through the Jefferson-Pilot Corporation. We are unclear as to whether or not this association will become a meaningful one in the coming months and years.

The mainstay of MSDIS remains the marketing of medical malpractice and workers' compensation insurance to our members. In this area we continue to be outstandingly successful. We have also been successful in selling the insurance to other physicians. Our share of the market has grown during this past year and, as a result of our success, MSDIS was able to declare a dividend of $100,000 to be distributed to the common stockholder, the Medical Society of Delaware. We look forward to declaring an additional dividend of $50,000 in December to be distributed to the common stockholder.

We anticipate that this operation will continue to be a highly successful one in the future. Revenues should increase during the next calendar year. This growth in revenues is a result of the misfortunes of our membership, who face ever-increasing insurance premiums. As the dollar values of these premiums increase, as they appear certain to do, MSDIS will accordingly earn more and more dollars.

Joseph E. Belgrade, M.D.
President

(The report was filed with commendation.)

SCHOOL HEALTH ADVISORY COMMITTEE, STATE OF DELAWARE

According to the 1985-86 year-end report of the School Health Advisory Committee, there has been good referral and follow-up for children showing problems with blood pressure, strep infections, pediculosis, hearing, and orthopedics. It was felt by your representative that physicians of the Medical Society should give 100% follow-up to all of the above problems.

In November a draft of "Smoking and the Use of

Tobacco Policy for Students and Adults" was confirmed and sent to the Chief School Officers. It was understood this would mean smoking, using tobacco products such as snuff and chewing tobacco, dispensing tobacco products, or selling tobacco products would be prohibited on school grounds during regular school hours and in all school buildings and buses at all times.

Four copies of the videotape on Tourette's Syndrome are now present in the Department of Public Instruction Film Library.

Immunizations are at a 96% level. There is some concern that the rising cost of vaccines may so burden parents that some children will be denied their vaccinations. The lowest actual cost for vaccine alone at present is $12.30. This needs pressure on Congress expressing parents' and physicians' concern.

In March the School Health Committee supported the AIDS program for presentation to high school seniors. At the same time the Medical Society of Delaware's push for Health Education was acknowledged.

The May meeting updated the AIDS program by using "AIDS—Learn for Your Life." Also a letter was sent to the Lake Forest School Board commending them for their action to ban smoking not only for students but also for the school staff.

President Reagan has signed into law "The Drug-Free Schools and Community Act of 1986." The School Health Advisory Committee appointed members to an ad hoc Drug Committee to comply to the needs expressed in the law. Ms. Susan Wooley was appointed chairman.

The second meeting of the ad hoc committee was addressed by Mr. Jeffrey Garland, special assistant to Governor Castle, of the Governor's Advisory Committee for Drug Abuse Prevention. Resources, a speakers' bureau, publications and communications to all citizens were the outlined methods to accomplish the mission in Drug Abuse Prevention.

Six meetings have been held by the ad hoc committee with the increasing possibility it will be a permanent committee. Workshops for teachers, students and the public are planned. Resources for aid to the victims of drug abuse are being established. Efforts will be made to develop counseling groups to conduct workshops. The theme from the Governor's advisory committee throughout is to get the accurate information to as many as possible because education will help society make the needed final decision.

To get the message to the physicians of Delaware. Jeff Garland has agreed to meet Delaware's physicians in their County Society Meetings.

Rhoslyn J. Bishoff, M.D.
Representative

(The report was filed with approval of the recommendation that the Board of Trustees review the policy of mandatory durg screening in the schools.)

THE SPINA BIFIDA ASSOCIATION OF DELAWARE

The Spina Bifida Association of Delaware, Inc., (SBAD), a Chapter of the Spina Bifida Association of America (SBAA), is a non-profit organization for parents, relatives, interested professionals, and friends of children or adults of all ages, born with Spina Bifida and related neural tube defects.

The primary function of SBAD is to be a support network for parents, relatives, and friends of a newborn affected with Spina Bifida. This support is carried throughout the years of medical care, education (mainstreaming or special education), and socialization to the post adolescent period of self-care and attainment of vocational goals.

The activities of the Spina Bifida Association of Delaware, in which the aid of health care professionals is of the utmost importance, include the following:

Parent outreach program. This program encourages referrals of parents, relatives and friends of Spina Bifida children or adults. Our members have a great deal of information and knowledge, through personal experience, to share with new parents, or anyone else interested in the Spina Bifida child or adult. We provide support and encourage referrals of parents, relatives, and friends of this special child or adult.

Guest speaker program. Specific types of programs have been of common interest among the members of our group even though our children are of different ages and have various degrees of disabilities. Some of these programs are as follows: socialization of the disabled child, development and treatment of hydrocephalus, physical therapy, genetic and enviromental causes of Spina Bifida, bowel/bladder programs, and mainstreaming of the Spina Bifida child or adult.

Young adult group. We are attempting to organize a youth group in which our young adults with Spina Bifida could participate, to provide a means of social support for each other.

Swimming program. Swimming lessons for Spina Bifida children are bing provided with the cooperation and support of the Alfred I. du Pont Institute of the Nemours Foundation and the Red Cross.

Additional programs. Other activities include: Monthly Mothers' Meetings; Corvette Club Auto Shows to benefit our organization; pioneers of the telephone company Annual Picnic for benefit of our members and families; development of a Spina Bifida Library to be available to all SBAD members, their families, and all other supportive parties; development of an Equipment Locker that would allow the distribution of needed equipment to the families of Spina Bifida children in a cost-effective manner and that would allow full use of said equipment; and other annual picnics and parties for the benefit of the organization's family members.

We encourage interested organizations to contact us and make arrangements for our organization to supply speakers to make informational presentations and answer questions concerning Spina Bifida.

We highly encourage those of you who actively deal with Spina Bifida children or adults to attend our meetings, either to add to your knowledge through our actual, first-hand experience of our members, or to share your wealth of knowledge of Spina Bifida with our members.

For further information on the SBAD, please call (302) 478-4805 or write to us at: The Spina Bifida Association of Delaware, P.O. Box 807, Wilmington, DE 19899.

Nina L. Steg, M.D.
Liaison

(The report was filed with a commendation to Dr. Steg for many years of excellent leadership.)

RESOLUTIONS

SUBSTITUTE RESOLUTION 87-1

Subject: Nursing Home Regulations

Whereas, nursing home regulations are formulated and later enforced without realistic concern for all participants, namely, patients, nurses, nursing home administrators, patient advocates, and physicians; and

Whereas, completed "paperwork" is the criteria used to evaluate nursing home care; and

Whereas, the most recent inspection regulations and nursing home interpretation have placed rigid dates and times for medical care; and

Whereas, these rigid time rules are unrealistic for all persons involved (including the patients); now therefore be it

Resolved, that the Medical Society of Delaware seek to establish in the confines of Delaware better understanding and cooperation among state and federal health agencies, nursing homes, physicians, and patient advocates to the betterment of the care of the nursing home patient; and be it further

Resolved, that the Medical Society of Delaware ask the American Medical Association to seek to establish better understanding and cooperation among federal health agencies as they make rulings that affect all fifty states' health agencies, nursing homes, physicians, and patient advocates to the betterment of the care of the nursing home patient.

Substitute Resolution 87-1 was adopted by the House.

RESOLUTION 87-2

Subject: Unified Membership

Whereas, the House of Delegates on November 14, 1986, narrowly approved a Bylaws change providing that membership in the American Medical Association or the American Osteopathic Association is mandatory for all Medical Society of Delaware members; and

Whereas, this requirement has created a schism within the membership of the Medical Society of Delaware; and

Whereas, a number of state medical society members have elected not to pay state/county/AMA dues for 1987; and

Whereas, the number of new physicians electing medical society membership has been less than anticipated; and

Whereas, a recent poll of the membership revealed that a majority of respondents were opposed to unified membership, with the final vote being 420 against unified membership and 301 in favor of unified membership; now therefore be it

Resolved, that the Medical Society of Delaware de-unify membership with the AMA beginning with the 1988 dues year; and be it further

Resolved, that an appropriate Bylaws change be adopted by the House of Delegates so that membership in the American Medical Association or the American Osteopathic Association is no longer mandatory for all Medical Society of Delaware members; and be it further

Resolved, that the Medical Society of Delaware encourage physicians on an individual basis to support the AMA and its efforts on behalf of medicine.

Resolution 87-2 was not adopted by the House.

SUBSTITUTE RESOLUTION 87-3

Subject: HMOs - Medical Policy

Whereas, health maintenance organizations are proving successful in Delaware; and

Whereas, in the coming years they will include an increasing share of clinical practice; and

Whereas, it remains vital that no commercial agency interpose itelf between patient and physician in medical matters; now therefore be it

Resolved, that the Medical Society of Delaware seek the cooperation of each insurance company or other agency which operates an HMO in Delaware to revise its plan of operation so that all medical policy (credentialing, patient care, peer review, etc.) be under control of a body of physicians, and that all insurance functions (marketing, collections, auditing, etc.) be under control of the company, and that this be an on-going cooperative relationship for the benefit of the patients.

Substitute Resolution 87-3 was adopted by the House.

RESOLUTION 87-4

Subject: Medical Care for the Needy

Whereas, modern science and technology have vastly increased the cost of medical care; and

Whereas, the Medical Society of Delaware always has been and continues to be concerned for the health of all the people of Delaware; including the poor; now therefore be it

Resolved, that the Medical Society of Delaware redouble its efforts to monitor the adequacy of government programs for the poor, and, independently of government and other third parties, initiate and coordinate voluntary programs for its physicians to provide medical care for the needy in Delaware.

Resolution 87-4 was adopted by the House.

SUBSTITUTE RESOLUTION 87-5

Subject: Health Education

Whereas, the State Board of Education has mandated Health Education in Delaware's public schools in grades K-12; and

Whereas, the increasing crises of teenage pregnancy, abuse of alcohol and drugs, and spread of the epidemic of AIDS and other sexually transmitted diseases in our state require that we implement immediately an effective program of health education in this state; and

Whereas, our elementary school teachers are currently very ill-prepared for teaching a substantive health education program; and

Whereas, health education courses are currently not a part of the University of Delaware's program for our elementary school teachers; now therefore be it

Resolved, that the Medical Society of Delaware urge Dr. Russel Jones, Dr. William Delauder, and Dr. Reed Stewart and their boards of trustees to stress health education as an integral part of the preparation of our

elementary and early childhood school teachers; and be it further

Resolved, that the Medical Society of Delaware urge the State Board of Education to initiate proceedings to make health education courses a requirement of certification of early childhood and elementary school teachers.

Substitute Resolution 87-5 was adopted by the House.

SUBSTITUTE RESOLUTION 87-6

Subject: Testimony Review Committee

Whereas, bearing false witness is unethical behavior; and

Whereas, doctors claiming to be experts under oath may produce widely varying medical testimony; and

Whereas, exaggerations of injuries create a climate for inflated awards in all types of civil litigation; and

Whereas, medically improper testimony constitutes unprofessional conduct; and

Whereas, the Medical Society of Delaware has an obligation to monitor the professional conduct of its members; and

Whereas, the physicians in Delaware have an interest in maintaining the integrity of the legal system by giving accurate medical information to the court; now therefore be it

Resolved, that the Medical Society of Delaware establish a format to review medical testimony made available to it in whatever form. The committee should make timely reports to the Board of Trustees. Where unethical behavior has been delineated, the Board of Trustees will report this to the Board of Medical Practice.

Substitute Resolution 87-6 was adopted by the House.

As a memorial to the members of the Society who were lost through death during the past year, the assembly rose for a moment of silence as the names were read:

Haynes B. Cates, M.D.
Joachim Chung-Chiu Chi'ih, M.D.
Norman L. Cutler, M.D.
J. Stites McDaniel, M.D.
Roger Murray, M.D.
John C. Pierson, M.D.
Isadore Slovin, M.D.
Arnold H. Williams, M.D.
Allen C. Wooden, M.D.

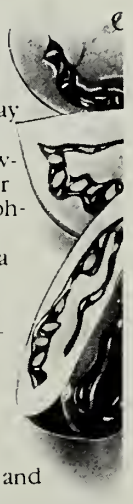
ABSOLUTION RESOLUTION

The House adopted the following resolution:

Resolved, that each and all of the Resolutions, acts, and proceedings of the Board of Trustees of the Medical Society of Delaware heretofore had been adopted since the last meeting of the House of Delegates of the Medical Society of Delaware as shown by the records of the minutes and all the acts of the officers and trustees of the Society in the carrying out and promoting of purposes, objects and interests of this Society since the last House of Delegates meeting are approved and ratified and hereby made the acts and deeds of the Medical Society of Delaware.

(The complete report of the Proceedings of the House of Delegates is on file in the Medical Society office and is available to members.)

A defense against cancer can be cooked up in your kitchen.



There is evidence that diet and cancer are related. Some foods may promote cancer, while others may protect you from it.

Foods related to lowering the risk of cancer of the larynx and esophagus all have high amounts of carotene, a form of Vitamin A which is in cantaloupes, peaches, broccoli, spinach, all dark green leafy vegetables, sweet potatoes, carrots, pumpkin, winter squash, and tomatoes, citrus fruits and brussels sprouts.

Foods that may help reduce the risk of gastrointestinal and respiratory tract cancer are cabbage, broccoli, brussels sprouts, kohlrabi, cauliflower.

Fruits, vegetables and whole-grain cereals such as oatmeal, bran and wheat may help lower the risk of colorectal cancer.

Foods high in fats, salt- or nitrite-cured foods such as ham, and fish and types of sausages smoked by traditional methods should be eaten in moderation.

Be moderate in consumption of alcohol also.

A good rule of thumb is cut down on fat and don't be fat. Weight reduction may lower cancer risk. Our 12-year study of nearly a million Americans uncovered high cancer risks particularly among people 40% or more overweight.

Now, more than ever, we know you can cook up your own defense against cancer. So eat healthy and be healthy.

No one faces cancer alone.

AMERICAN CANCER SOCIETY

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of Presbyterian-University of Pennsylvania Medical Center

CARDIOLOGY UPDATE . . .

is designed for the Physician and provides an intensive survey of the current status of Clinical Cardiology . . .

WEDNESDAY, MARCH 2, 1988

DIAGNOSIS AND MANAGEMENT OF NON-CORONARY DISORDERS

MODERATOR: Bernard L. Segal, M.D.

3:00 to 3:20	Cardiac involvement in anemias and connective tissue disorders - Warren Katz, M.D.
3:20 to 3:40	The athlete and the heart - Garo S. Garibian, M.D.
3:40 to 4:00	Congenital heart diseases in the adult - Bernard L. Segal, M.D.
4:00 to 4:30	Case presentations - Jonathan Gomberg, M.D.
4:30 to 5:00	Panel Discussion - Michael V. Yow, M.D., Ami S. Iskandrian, M.D.

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- No Advance Registration Required
- CME Credits*

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Book Reviews

William L. Jaffee, M.D., Book Review Editor

NEW EDITOR

Dr. William Jaffee has recently assumed the post of Book Review Editor. Let him know what books you'd like to review or see reviewed. Our thanks to retiring Dr. Wayne Martz, who has done a wonderful job for many years.

PHYSICIANS OBSERVED, by **David R. Slavitt.** 1987; Garden City, New York: Doubleday & Company. 255 pages. Price $17.95.

In *Physicians Observed*, David Slavitt takes a look at various nonmedical aspects of being a a physician. Slavitt, who is an editor, journalist, and author is married to a hematologist and has a daughter in medical school. This places him in a unique position for interviewing physicians in his attempt to explain the ways that personality development may be limited by the demands of medicine. He guides us through the process of becoming a physician: the undergraduate premed years, the medical school application process and the ensuing four-year grind, specialty training, and, finally, practice, with its attendant difficulties. Throughout this trek, which may ring all too familiar, the author's underlying theme is that physicians, for the most part, have not developed the caring, nurturing, and most humane elements of their personalities. He feels that people in medicine have neglected (or have been pressured to neglect) these facets of their lives for the sake of pursuing the goals of a career in medicine.

The author deals with specific problems of contemporary interest, such as physician impairment due to addiction, by attempting to research and comprehend the underlying causes--and never in a judgmental fashion. In light of the increasing numbers of female physicians these days, the chapter on women is especially pertinent, and considering his exposure to women in medicine in his own family, Slavitt is particularly qualified to comment on the struggles peculiar to women in the field. He speculates in turn as to the beneficial effect women have had on the practice of medicine.

Although the entire range of situations described in the book will of course not reflect the experience of every reader, it is certain that at some point(s) in the book each physician reader will recognize a little of himself. Slavitt's intent is not to indict physicians, but rather to encourage them to look at their own lives, to recognize where there are deficiencies, and to take appropriate steps to remedy shortcomings. The author's singular purpose in writing this book would appear to be to aid physicians to become better doctors by becoming better human beings.

My recommendation is for the physician to read this very relevant and most thought-provoking book. In addition, the nonphysician reader may acquire some insight into dilemmas physicians can encounter, which should help promote understanding and thus, it is hoped, ultimately enhance the doctor-patient relationship.

Carl T. Opderbeck, M.D.

MEDICAL PRACTICE SALES AND APPRAISALS

We specialize in the valuation and selling of medical practices. If interested in buying or selling a medical practice contact our Brokerage Division at The Health Care Group, 400 GSB Building, Bala Cynwyd, Pa. 19004 (215) 667-8630.

SOFT TISSUE RHEUMATIC PAIN: RECOGNITION, MANAGEMENT, PREVENTION, by **Robert P. Sheon, M.D., Roland W. Moskowitz, M.D.,** and **Victor M. Goldenberg, M.D.** 1987; Philadelphia: Lea and Febiger. Price: $42.50.

This is the second edition of a text first published in 1982, and at that time quite well received. This text is slightly longer, reflecting our increasing understanding of soft tissue rheumatic syndromes and our ability to intervene positively in these problems. The second edition increases practical information and provides additional emphasis on problems arising in sports and in the workplace. Additional references are provided that review efficacy of treatment and provide information regarding new diagnostic and treatment techniques. The various tables and photographs have been improved and clarified. My feeling is that the authors have done an admirable job improving on an already helpful text. Whether you are interested in TMJ syndrome or torticollis; shin splints or plantar fascitis; Tietze's syndrome, fibromyalgia, or hypermobility, this text provides useful information. It is valuable for the general practitioner or internist, and I would recommend it for your library.

James H. Newman, M.D.

TEXTBOOK OF GENERAL MEDICINE AND PRIMARY CARE, edited by **John Noble, M.D.** 1987; Boston: Little, Brown & Company. 2376 pages. Price $85.00.

The editor of this book is a professor of medicine at Boston University School of Medicine, and Director, Primary Care Center, Boston City Hospital.

This book is the careful result of a deliberate goal to write a reference text which would answer the needs of the busy primary care physician, as opposed to the needs of the academician. "The clinical presentation and management of illness and medical problems of primary care as it is actually practiced...has served as the major focus of this text." The editor refused to go along with the prevailing belief that most of the really sick patients are treated by internists in teaching hospitals and that primary care physicians in the field are not knowledgeable. He spent one year on sabbatical from his professorship in an active rural primary care practice. He recorded all his cases and used them as the organizational basis for the textbook. He then assembled a group of 200 physicians to go along with his philosophy. The result is a reference text which bypasses the esoteric and stresses the practical. In addition to the customary chapters arranged by organ system disorders, the book includes others such as "Concepts of Health and Disease," "Ethics for the Primary Care Physician," "Supportive Care for the Patient with Cancer," "Social Determinants of Cardiovascular Disease," "Family Life Cycle," "Menstrual Abnormalities," "The Raped and Battered Patient," "The Homosexual Patient," "Alcoholism and Substance Abuse," "The Malnourished Patient," and a host of others.

This book is pleasantly readable and a first rate reference text for the busy primary care on-the-line physician.

David Platt, M.D.

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Leading authorities in the non-invasive diagnosis of myocardial infarction, coronary angiography, PTCA, coronary bypass surgery, drug therapy, thrombolysis and post-MI stress testing have been retained as faculty for this symposium.

Please join us Sunday, February 28th, 1988, in the Christiana Ballroom of the Christiana Hilton Inn, immediately off Interstate 95 exit 4 North, at Delaware Route 7. This symposium has been accredited for 8 hours of Category 1 continuing medical education credit toward the Physician's Recognition Award of the American Medical Association by Thomas Jefferson University/Jefferson Medical College.

Registration and a continental breakfast begin at 8 a.m. and a luncheon will be served. Advance registration fee $15; registration fee on-site $20.

For further details, or to register by telephone, please contact Jacki Biddle at (302) 366-1929. The Program Director is Dr. Andrew Doorey.

The Medical Center of Delaware

Department of Medicine/
Section of Cardiology

and

Thomas Jefferson University | Jefferson Medical College

X-013, 2/88

YOCARDIAL INFARCTION – 1988

PROGRAM *February 28, 1988 — The Christiana Hilton Inn*

8:15 – 9:00	Registration and Continental Breakfast.
9:00 – 9:05	Welcome *Dr. Alfred Bacon, Jr.*
9:05 – 9:20	Overview: The Problem of Acute Myocardial Infarction, 1988. *Dr. Andrew Doorey*
9:20 – 9:45	Non-invasive Diagnostics in Acute Myocardial Infarction, Echocardiography, Radioventriculography (MUGA), Technetium Scanning. *Dr. Barry Denenberg*
9:45 – 10:10	Pharmacologic Therapy of Acute Myocardial Infarction—Pressor Agents, Lidocaine, Anticoagulants. *Dr. Ehsanur Rahman*
10:10 – 10:40	Coffee Break
10:40 – 11:15	The Clinical Use of Thrombolysis in Acute Myocardial Infarction — The Harvard Approach. *Dr. James Kirshenbaum*
11:15 – 11:40	Coronary Angiography after Myocardial Infarction — Who Needs It? When Should It Be Done? *Dr. Edward Goldenberg*
11:40 – 12:00	Panel Discussion *Drs. Denenberg, Goldenberg, Kirshenbaum, Rahman.*
12:00 – 1:00	Lunch
1:00 – 1:40	PTCA in Acute Myocardial Infarction. *Dr. Andrew Doorey*
1:40 – 2:20	Early Stress Testing After Myocardial Infarction. *Dr. Arthur Colbourn*
2:20 – 2:50	Coronary Bypass Surgery during or shortly after Myocardial Infarction. *Dr. Gerald Lemole*
2:50 – 3:15	Coffee Break
3:15 – 3:45	The Pathophysiology of Pharmacologic Therapy after Myocardial Infarction — Beta Blockers, Calcium Channel Blockers, Aspirin. *Dr. Michael Stillabower*
3:45 – 4:30	Thrombolysis in Community Hospitals and Triage for Rapid Definitive Therapy — The Michigan Experience. *Dr. Eric Bates*
4:30 – 5:00	Panel Discussion *Drs. Bates, Doorey, Lemole and Stillabower.*

Deaths

GUIDO ASCANIO, M.D.

Dr. Guido Ascanio, a family practitioner in Seaford and Laurel, Delaware, died January 7, 1988, in Nanticoke Memorial Hospital. He was 65.

Dr. Ascanio graduated from the Havana University School of Medicine in 1949. He engaged in private practice in Cuba until 1960, when he emigrated to the United States. He lived in the Philadelphia area, and was an Associate Professor in the Department of Physiology at Temple University Medical School from 1960 until 1976, then reengaged in private practice in Drexel Hill from 1976 until 1982.

In January, 1983, Dr. Ascanio began his private practice in Laurel. He was an active member of the Medical Staff of Nanticoke Memorial Hospital, and was also employed as a physician at the Methodist Manor House in Seaford. Dr. Ascanio was in practice until he was hospitalized with a sudden illness on December 5, 1987. He was a member of the Sussex County Medical Society, the Medical Society of Delaware, and the American Medical Association.

Dr. Ascanio will be missed by his colleagues at Nanticoke Memorial Hospital where, as a consummate teacher, he was well-known for sparking medical discussions. He will be particularly missed by the residents and staff at the Methodist Manor House, where his reputation as a caring and devoted physician was most appreciated.

Jacqueline S. Alvarez

FRANCIS W. GODWIN, M.D.

Dr. Francis W. Godwin, a Wilmington obstetrician and gynecologist for almost 30 years, was found dead in his home in Greenville on February 1, 1988. He was 57.

Dr. Godwin was a summa cum laude graduate of University of Delaware, where he was a member of Phi Beta Kappa. He was a 1960 graduate of University of Virginia Medical School. He was a diplomat of the American Academy of Obstetrics and Gynecology, and a member of the New Castle County Medical Society, the Medical Society of Delaware, and the American Medical Association.

Dr. Godwin was well-known as a certified flight instructor at Dawn Aeronautics, Inc., and as a certified commercial pilot. He was responsible for teaching many local professionals how to fly.

CHARLES M. MOYER, M.D.

Dr. Charles Moyer, formerly of Laurel, Delaware, died January 11, 1988, in Sarasota, Florida, while playing golf. He was 77.

Dr. Moyer was a 1931 graduate of Dickinson College in Pennsylvania, and a 1936 graduate of Temple University School of Medicine. He began his practice in family medicine in Laurel in 1938, working out of his home for many years. His special interest was in cardiovascular disease. Dr. Moyer retired in 1986 and moved to Sarasota for health reasons.

He was on staff at Beebe Hospital in Lewes and Peninsula Medical Center in Salisbury, Maryland, and was chief of staff at Nanticoke Memorial Hospital in Seaford. Dr. Moyer was a member of the American College of Cardiology, the American Medical Association, the Medical Society of Delaware, and Sussex County Medical Society. He was a past president of both the Medical Society of Delaware and the Sussex County Medical Society. He was a member of the State Board of Health and served a term as its vice president

A resolution expressing acknowledgment and appreciation of Dr.Moyer's contributions to society and the state was introduced in the Delaware House of Representatives.

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In Brief

IMPAIRED PHYSICIAN COMMITTEE

DO YOU KNOW AN IMPAIRED PHYSICIAN OR A PHYSICIAN IN TROUBLE? The Physicians' Health Committee wishes to help. Please call (302) 654-1001. The anonymity of the caller is assured.

CLINICAL MEETINGS AND NOTICES

MARYLAND MEETING

The Maryland Academy of Family Physicians will hold their 40th Annual Meeting and Scientific Session May 11-15, 1988 at the New Sheraton Fountainbleu Inn and Spa in Ocean City, Maryland. The program is approved for up to 32.75 hours of AAFP prescribed credit. For brochure and registration information, contact the Maryland Academy of Family Physicians, 5700 Executive Drive, Suite 110, Baltimore, Maryland, 21228, or call 301-747-1980.

INFECTIOUS DISEASE SYMPOSIUM

The 25th Annual Infectious Disease Symposium will be held May 2-6, 1988, at the Delaware Academy of Medicine Building. For more information, contact Dr. William J. Holloway, Infectious Disease Research, The Medical Center of Delaware, PO Box 1668, Wilmington, Delaware, 19899, or call 302-428-2744.

WORKSHOP IN SURGICAL TECHNIQUES

The 11th Annual Workshop in Surgical Techniques in Cleft Lip and Palate will be held March 13-19, 1988 at The Snowmass Club, Snowmass, Colorado. The workshop is accredited for up to 27.5 credit hours in Category I of the AMA. For more information, contact Dr. Janusz Bardach, the University of Iowa Hospitals and Clinics, Iowa City, Iowa, 52242, or call 319-356-2168.

COMPUTER APPLICATIONS IN RADIOLOGY

Hilton Head Island will be the site of the Ninth Conference on Computer Applications in Radiology on June 1-4, 1988. This course has been accredited for up to 21 hours in Category I of the AMA. For more information, contact Janice Ford, Continuing Education Coordinator, Department of Radiology, Hospital of the University of Pennsylvania, 3400 Spruce Street, Philadelphia, Pennsylvania, 19104, or call 215-662-6904.

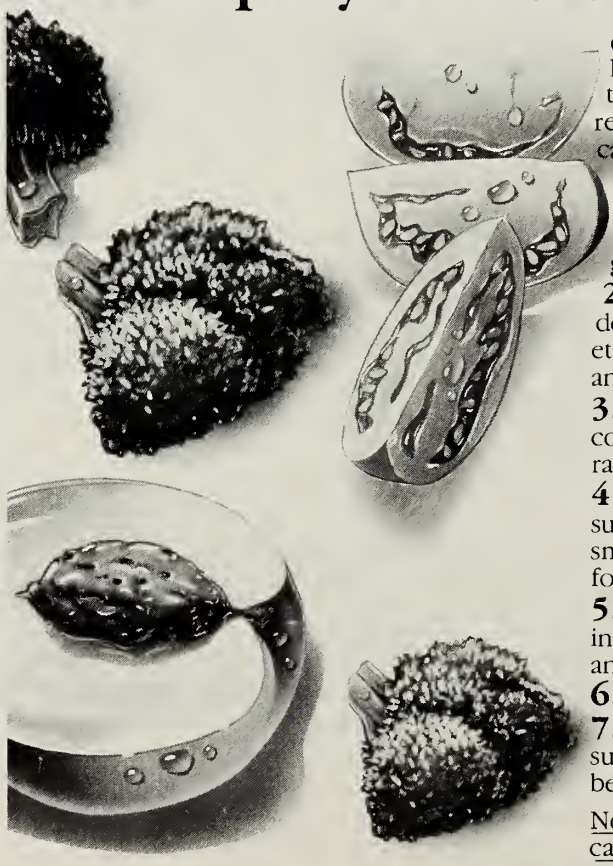
AIDS CONFERENCE

Mark your calendars for an all-day Conference on AIDS, to be held Saturday, April 16, 1988, at Clayton Hall, University of Delaware. The sponsors are the Medical Society of Delaware, the Delaware State Dental Society, and the Delaware State Bar Association. National speakers have been contacted to speak on AIDS-related problems concerning all professionals today. The morning session will address the special interests of the dental and medical professionals, and the afternoon will be devoted to legal issues surrounding the AIDS patient. More information will be forthcoming.

DELAWARE FAMILY PHYSICIANS MEETING

The 36th Annual Meeting and Scientific Session of the Delaware Academy of Family Physicians will be held March 25-26, 1988, at the Delaware Academy of Medicine Building, and the Ramada Inn in New Castle. On Friday night, there will be a dinner and annual business meeting, followed by Lewis W. Bluemle, Jr., M.D., President of Thomas Jefferson University, speaking on "Leadership Role of Family Physicians in Preventive Medicine," On Saturday the all-day scientific session will start with registration at 8:15 a.m., and feature five lectures and a panel discussion. For more information, contact the Delaware Academy of Family Physicians, 1925 Lovering Avenue, Wilmington Delaware, 19806 or call 302-658-7596.

A defense against cancer can be cooked up in your kitchen.



There is evidence that diet and cancer are related. Follow these modifications in your daily diet to reduce chances of getting cancer:

1. Eat more high-fiber foods such as fruits and vegetables and whole-grain cereals.
2. Include dark green and deep yellow fruits and vegetables rich in vitamins A and C.
3. Include cabbage, broccoli, brussels sprouts, kohlrabi and cauliflower.
4. Be moderate in consumption of salt-cured, smoked, and nitrite-cured foods.
5. Cut down on total fat intake from animal sources and fats and oils.
6. Avoid obesity.
7. Be moderate in consumption of alcoholic beverages.

No one faces cancer alone. AMERICAN CANCER SOCIETY

President's Page

IT'S EVERYBODY'S JOB

On page of 145 of this issue is a report to the members of the Society from Dr. William Duncan, our elected trustee to the West Virginia Medical Institute. Dr. Duncan has been serving in this role since February, 1987. Each month he provides to the Board of Trustees of the Medical Society of Delaware a comprehensive report on his activities as the WVMI Delaware Trustee. I have asked him to share with all of you this information.

Over the past few years, this and many other medical journals have delt with significant items of concern regarding federal intervention in many of the aspects of the practice of medicine. Many mandatory requirements recommended by the federal government have been vigorously opposed on these pages. However, many requirements have been implemented and the Professional Review Organization (PRO) is one of these that we must now live with on a day to day basis. We should be pleased to learn from Dr. Duncan that the Trustees of WVMI and their committees demonstrate understanding and insight regarding the problems of the practicing physician. WVMI has been responsive to our concerns and requests for information. We must keep these avenues of communication active and open. Although the answers we may receive receive may not always be what we would ideally prefer, they have been researched and thoroughly investigated by Dr. Duncan.

The hospitals and physicians of Delaware are fortunate to have someone of his ability, energy, and concern to represent us on the Board of the West Virginia Medical Institute. We must, however, actively assist and support Dr. Duncan in his efforts by volunteering to become PRO reviewers. This sometimes onerous task demands our active participation and involvement. It's everybody's job.

Martin J. Cosgrove, M.D.

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BRIEF SUMMARY

CONTRAINDICATIONS
There are no known contraindications to the use of sucralfate.

PRECAUTIONS
Duodenal ulcer is a chronic, recurrent disease. While short-term treatment with sucralfate can result in complete healing of the ulcer, a successful course of treatment with sucralfate should not be expected to alter the post-healing frequency or severity of duodenal ulceration.

Drug Interactions: Animal studies have shown that the simultaneous administration of CARAFATE with tetracycline, phenytoin, or cimetidine will result in a statistically significant reduction in the bioavailability of these agents. This interaction appears to be nonsystemic in origin, presumably resulting from these agents being bound by CARAFATE in the gastrointestinal tract. The bioavailability of these agents may be restored simply by separating the administration of these agents from that of CARAFATE by two hours. The clinical significance of these animal studies is yet to be defined.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No evidence of drug-related tumorigenicity was found in chronic oral toxicity studies of 24 months' duration conducted in mice and rats at doses up to 1 gm/kg (12 times the human dose). A reproduction study in rats at doses up to 38 times the human dose did not reveal any indication of fertility impairment. Mutagenicity studies have not been conducted.

Pregnancy: Pregnancy Category B. Teratogenicity studies have been performed in mice, rats, and rabbits at doses up to 50 times the human dose and have revealed no evidence of harm to the fetus due to sucralfate. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when sucralfate is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS
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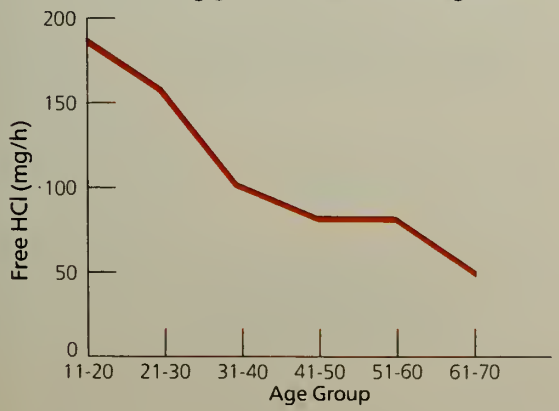

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Special Report:

THE WVMI PRO AND DELAWARE PHYSICIANS

Since my election as the Delaware Trustee to the West Virginia Medical Institute, I have attended seven of the nine scheduled meetings, generally all day affairs held on Sundays in the WVMI offices in Charleston, West Virginia. It is important for the membership of the Medical Society of Delaware to know that not only is WVMI the Professional Review Organization (PRO) for Delaware, but that it also holds the contract with the State of Delaware to perform Medicaid review.

Two thirds of each monthly meeting is spent on sanction. The sanction review and sanction process is serious business. Based on my attendance at these meetings, I believe that the interest and concern displayed on the part of the Trustees of the WVMI to the information presented on which action is taken, and their personal interview process with both practicing physicians and the hospitals, is both understanding and compassionate. It also follows due process. I have found this also to be true in the meetings of the different committees of WVMI that I attended as part of my orientation to the Board.

During this time, there has been one sanction proceeding committed in Delaware. Whether additional actions will be necessary in the future, only time will tell. There is significant data regarding practice patterns of both physicians and hospitals in Delaware available since April, 1987. This data is generated in four reports: utilization summary by DRG, utilization summary by attending physician, basic utilization profile by provider (hospital), and DRG profiles showing reviews and quality problems by severity level.

Review of these reports does not indicate any significant deficiencies or trends; however, this primarily is data from 1986 and early 1987 admissions, and not sufficient data from which to draw any conclusions. As is true of all PROs, as trends and other factors are developed from these reports, they will be reported and appropriate actions suggested, if only generically, through the Medical Society of Delaware.

In Delaware, there are currently 48 physician reviewers who include most specialties and subspecialties. But as is true of any organization which hopes to provide a broad objective base, I strongly suggest that each physician in Delaware volunteer as a specialty or subspecialty reviewer.

The four mandated PRO committees (Sanction, Quality, Utilization Review, and Education) have been appointed with all Delaware physicians in Delaware. The Quality Committee will be the most active, and since I am your elected Trustee, I volunteered to be the chairman. All actions taken are actions of the full committee after thorough discussion, review, and formal voting procedures. The reason I stress this is, letters of concern or recommendations for actions about physicians' practice patterns may soon be forthcoming from the Quality Committee, letters which for the most part will probably be signed by me. I ask you to accept them at face value; there is nothing surreptitious going on. If you are a recipient of such a letter, please respond in an appropriate manner to

actions and the recommendations therein.

Since February, 1987, I have received seven formal and specific inquiries from the membership on a myriad of subjects. The answers in all instances were perhaps not what the inquiring physician would have wanted, but I made a sincere and conscientious effort to answer or have answered each of these inquiries in an objective and intelligent manner.

Following are a number of miscellaneous items which may be of interest to the membership:

WVMI has been preselected as the HMO review agency for Delaware at such time as HMO review might be required.

A detailed physician reviewer handbook is being prepared and will be provided to each physician reviewer. In addition, an educational program is being developed which will be videotaped for use by the physician reviewers. Its scope is such that it could perhaps be of benefit to all hospital medical staffs.

Another item of business at the WVMI has been a resolution in the bylaws mandated by recent federal legislation to include a representative of consumers on the governing body of WVMI.

Each month the financial report indicates, not unlike other medical organizations in which all of us have been involved, insufficient funds to do all the things that WVMI would like to do and perhaps should do. The Board looks carefully at the report every month and uses it to set appropriate priorities.

WVMI has the same federal oversight bureaucratic difficulties as many of you who are familiar with DELRO remember that it had.

As you all may be aware, HCFA has announced that it has and will continue to release outcome data, primarily on mortalities. The proposed system will bypass the PRO in that HCFA will send this data to the hospital 30 days before releasing it to the public so that the hospital will be prepared to respond. I suggest you get involved in this matter in your own hospital.

The first "super PRO" evaluation report for Delaware has been completed from a sample of 271 cases. The super PRO agreed with WVMI in all categories from a low of 82.2% in DRG assignment to 100% agreement on premature discharge. The other categories reviewed were referral decisions, necessity of admission, and quality of care. Figure 1 represents the generic quality screens that are used during the review of all patients undergoing review and Figure 2 represents the severity index based on patient outcome which is the classification used in determining what recommendations should be made in individual cases under review.

HCFA's REVISED GENERIC QUALITY SCREENS

1. **Adequacy of discharge planning**
   Na dacumented plan for apprapriate follow-up care ar discharge planning as necessary, with consideration af physical, ematianal, and mental status/needs at the time af discharge.
2. **Medical stability of the patient at discharge**
   a. B P an day before ar day af discharge systalic — less than 85 or greater than 180 diastolic — less than 50 ar greater than 110
   b. Temperature an day before ar day af discharge greater than 101 degrees oral (rectal 102 degrees)
   c. Pulse less than 50 (ar 45 if the patient is on a beta blacker), ar greater than 120 within 24 haurs af discharge
   d. Abnarmal results of diagnastic services which are not addressed ar explained in the medical recard
   e. IV fluids ar drugs an the day of discharge (excludes KVOs, antibiotics, chematherapy, or total parenteral nutritian)
   f. Purulent ar bloady drainage af postaperative waund within 24 haurs prior to discharge
3. **Deaths**
   a. During ar fallawing elective surgery
   b. Fallawing return ta intensive care unit, coranary care ar special care unit within 24 hours af being transferred aut
   c. Other unexpected death
4. **Nosocomial infections**
   a. Indication of an infection fallowing an invasive pradecure (i.e., suctianing, catheter insertian, tube feedings, surgery)
   b. Temperature increase of more than 2 degrees mare than 72 haurs from admission
5. **Unscheduled return to surgery within same admission for same condition as previous surgery or to correct operative problem (exclude "staged" procedures)**
   Unplanned removal or repair of a normal organ (i.e., remaval ar repair not addressed in aperative consent)
6. **Trauma suffered in the hospital**
   a. Fall with injury ar untoward effect (including but not limited ta fracture, dislacatian, concussion, laceratian, etc.)
   b. Life-threatening complicatians of anesthesia
   c. Life-threatening transfusion error or reaction
   d. Hospital acquired decubitus ulcer
   e. Care resulting in seriaus ar life-threatening camplications, not related to admitting signs and symptams, including but nat limited ta the neuralagical, endacrine, cardiovascular, renal ar respiratary body systems (e.g., resulting in dialysis, unplanned transfer to special care unit, lenghtened haspital stay).
   f. Majar adverse drug reactian ar medicatian errar with seriaus potential far harm or resulting in special measures to carrect (e.g., intubation, cardiopulmonary resuscitatian, gastric lavage) including but nat limited to the following:
      I. incarrect antibiatic ardered by the physician (e.g., incansistent with diagnastic studies ar the patient's history of drug allergy).
      II. Na diagnostic studies to confirm which drug is carrect ta administer (e.g., C&S).
      III. Serum drug levels nat perfarmed as needed
      IV. Diagnastic studies ar ather measures far side effects nat perfarmed as needed (e.g., BUN, creatinine, intake and output)

* PRO reviewer is to recard the failure af the screen, but need not refer to physician reviewer.

SEVERITY INDEX
BASED ON PATIENT OUTCOME

CLASS I	Failure to support by appropriate evidence the medical necessity and quality of the care rendered to the Medicare beneficiary.
CLASS II	Medical mishap and/or mismanagement resulting in the *potential* for adverse patient outcome; patient medically stable upon discharge or transfer.
CLASS III	Medical mishap and/or mismanagement resulting in the *potential* for adverse patient outcome; patient medically unstable upon discharge or transfer.
CLASS IV	Medical mishap and/or mismanagement resulting in *actual* adverse patient outcome requiring additional medical and/or surgical treatment.
CLASS V	Medical mishap and/or mismanagement resulting *in disabling and/or dismembering injury* to body or mind, or death (which otherwise might not have been expected to occur).
ADDENDUM	Premature discharges will always be ranked as Severity Class IV or above dependent upon the circumstances of the case. Cases specific to the provisions of 3010.b through d of Transmittal V will be ranked according to patient outcome.

WVMI received a letter from the Office of the Inspector General of the Department of Health and Human Services announcing a national study of peer review organizations. As part of this venture, the Inspector General visited and surveyed 12 states, one of which was Delaware.

The WVMI Board has carefully followed and received presentations on litigation concerning PRO activities, particularly in Virginia.

The Fiscal Year 1987 WVMI statistics (did not include Delaware, but are reported for obvious historical interest) showed a 4% utilization denial rate, a 0.31% admission denial rate, and a 4.65% DRG change rate.

I presided over the first and so far only meeting of the Delaware Quality Assurance Committee, where four quality problems were reviewed and acted upon. For the first case considered, a "gross a nd flagrant" deficiency was confirmed. In one case the committee disagreed with the physician reviewer and reclassified the deficiency. In another case there was apparently substandard care, but there was not agreement as to responsibility, so both the physician and the hospital were requested to take appropriate action. And, a similar situation was present in the fourth case. All in all, I can report to you that the Delaware Committee was most dedicated and conscientious in their approach to this duty.

It was most interesting to the members about the point system and evaluation used in the 1984-1986 contract that was the basis for the 49 PROS that were evaluated. They were evaluated on a point scale, maximum points of which were 1,000. WVMI was first with 926 points. Delaware was thirty-first with 600. Interestingly, but disappointing to me as a former DELRO Board member, is that of the 18 PROs ranked under DELRO, ten of them were renewed in their contract, including those ranked 47, 48, and 49. It seems even more appropriate to me now that we should have gone to the mat with HCFA to try to maintain our own Delaware contract.

WVMI holds the Delaware Medicaid Contract through June of 1988.

On-site review of federal patients in nursing homes, outpatient departments and home health agencies will soon commence.

The PRO sanction procedures have recently been revised to permit what is perceived as greater "time process" for physicians.

The WVMI Board of Trustees shows great support for practicing physicians.

I have continued to talk on the phone and meet individually with our members concerning the activities of WVMI. I have also visited with individual physicians up and down the state concerning WVMI and will attempt to continue to provide this personal service. If you are interested in the activities of WVMI, please drop me a note stating your interest, your specialty and any special interest which you may have by sending this information in care of the Medical Society of Delaware, and I will see that you become involved and will be happy to nominate you as a physician reviewer.

William H. Duncan, M.D.

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FEEDING THE LOW BIRTH WEIGHT INFANT

Mary Lavelle Spear, B.S.N.
Michael L. Spear, M.D.

Introduction

Nutrition is an essential element in the care of the low birth weight (LBW) infant. The accelerated growth rate and greater nutritional requirements of infancy are even more pronounced in the premature, LBW infant. Survival of these infants has been achieved only over the past two decades, so guidelines for feeding and nutrient requirements are not well established. On top of baseline nutritional requirements, this infant usually experiences the added stress of illness.

Background

To understand the limitations in feeding the LBW infant, it is important to discuss the constraints of prematurity and low birth weight and their nutritional implications.

Respiratory Distress Syndrome (RDS) remains the leading cause of neonatal mortality and morbidity. Immaturity of the lung is the decisive factor of gestational viability at this time. Prior to 25 weeks gestation, airway and capillary proliferation is insufficient for gas exchange; therefore, an infant born at 24 weeks or less rarely survives. An infant with RDS has immature lungs which result in a surfactant deficiency, which causes atelectasis (alveolar collapse). Progressive atelectasis results in profound changes in ventilation, metabolism, and histology.[1]

Until recent years, the conventional management of RDS has consisted of assisted ventilation. This technique is used to facilitate ventilation/perfusion homogeneity to achieve adequate oxygenation during the first days or weeks of life. Caution must be taken to avoid complications of this therapy such as barotrauma, impaired cardiac output, and intraventricular hemorrhage. In an attempt to find alternatives to this potentially damaging therapy, artificial surfactant therapy is currently under investigation. Since the etiology of Respiratory Distress Syndrome is surfactant deficiency, exogenous supplementation would theoretically ameliorate this disease state. Presently under multi-center collaborative investigation, surfactant is instilled into the infant's lungs soon after birth. The preliminary results have demonstrated acceleration of lung maturity and shortened duration of mechanical ventilation. In this particular group of infants, nutrition is essential for increasing the rate of recovery. Early nutritional support can prevent negative nitrogen balance; initially, parenteral nutrition is used, followed by enteral feeds as the infant's condition stabilizes and the premature gastrointestinal tract can tolerate substrate.

Ms. Spear, previously a member of the Nutritional Support Team at The Children's Hospital of Philadelphia, is currently enrolled in a Master's program in Maternal-Child Nursing at the University of Delaware.

Dr. Spear is an attending neonatologist, Department of Pediatrics, at The Medical Center of Delaware, and an assistant professor of Pediatrics at Jefferson Medical College, Philadelphia.

Bronchopulmonary dysplasia is described as the pulmonary disease following RDS, as a result of lung immaturity, injury from mechanical ventilation, oxygen toxicity, and time.[2] Bronchopulmonary dysplasia involves not only the early injuries, but also delayed healing time. Early nutrition is thought to be important in preventing or ameliorating the disease.

Necrotizing enterocolitis (NEC) affects 3-5% of neonates requiring intensive care; 80% of affected infants are low birth weight. Although undocumented, many investigators believe a primary causative factor is intestinal hypoperfusion with mucosal injury. The hypoperfusion may be the result of shock and/or asphyxia. The development of NEC and feeding are thought to be related, since the disease rarely occurs in the unfed infant. The major issues regarding feeding are when to initiate feeds, the proper volume, and osmolarity. Intestinal colonization with certain pathogenic bacteria has also been associated with the development of NEC.[3] This is a potentially life threatening disease and should be guarded against in any stressed infant. Delayed enteral feedings, while using the parenteral route, for 48-72 hours in susceptible infants, has been shown to allow healing of intestinal mucosa in adults after hypoxic injury.[3] NEC sometimes requires surgical resection of the affected bowel. Postoperative management consists of parenteral nutrition with gradual progression to an elemental formula.

Retinopathy of prematurity (ROP) is comprised of abnormalities of the retinal capillary bed, including vascular congestion, tortuosity, dilatation, and arteriovenous shunting. The most severe form causes retinal detachment and blindness.[4] Classically, ROP has been considered an iatrogenic disease caused by oxygen overuse in premature infants. However, numerous researchers have observed ROP in term infants and others never exposed to oxygen therapy.[4,5] Lucey, et al, hypothesize that ROP is the result of a developing retina, highly sensitive to any disturbance in oxygen supply. These disturbances are many and sometimes uncontrollable with present methods of neonatal intensive care. Factors implicated in ROP include hyperoxia and hypoxia, blood transfusion, infection, hypercarbia, apnea, intraventricular hemorrhage, vitamin E deficiency, prenatal complications, and genetics. ROP remains difficult to prevent, treat, or investigate.

The nutritional implication of ROP is the role of vitamin E. As will be discussed, there is tremendous controversy over whether supra-normal levels of this vitamin ameliorate or prevent the progression of this disease.

Feeding the Low Birth Weight Infant

The nutritional goals when feeding the low birth weight infant are initially to prevent negative nitrogen balance and then to promote growth. Optimal growth is considered the rate of growth expected had the infant remained in utero. Intrauterine growth rates are attained with difficulty because of such limiting factors as fluid tolerance, patent ductus arteriosus, acidosis, and necrotizing enterocolitis. It has been reported that prolonged neonatal caloric deprivation is associated with decreased head growth and lower developmental scores in premature infants evaluated at one year of age.[6]

The nutritional requirements of the low birth weight infant remain unclear. This section will review current recommendations in enterally fed infants (Table 1).

Energy

Reichman, et al, were able to demonstrate weight gain equal to intrauterine rates in LBW infants while feeding them approximately 148 kcal/kg/day.[7] This growth rate was achieved in LBW infants maintained in a neutral thermal environment. Body composition of these infants differed from comparable in utero fetuses. The fetus has a higher percentage of water per total body weight, while the premature infant has a higher percentage of fat per total body weight. The increased fat accretion in the LBW infant is thought to be adaptive to its postnatal environment, and is similar to that observed in the term neonate's first four months of life.[7] Energy requirements are modified by differences in the infant's activity, environment, and health. As with adults, infection, respiratory distress, and surgery increase nutritional needs above normal.

TABLE 1
FEEDING THE LOW BIRTH WEIGHT INFANT

NUTRITION COMPONENT	APPROPRIATE INTAKE
CALORIES	148 kcal/kg/day
PROTEIN	2.5-4 gm/kg/day
CARBOHYDRATE	Lactose, glucose polymers
FAT	Medium and long chain triglycerides
CALCIUM	200-250 mg/kg/day
PHOSPHORUS	100-200 mg/kg/day
VITAMIN E (maintenance)	25-100 IU/day
IRON	2 mg/kg/day
FOLATE	50 mcgm/day
ZINC	0.5 mcgm/kg/day
COPPER	90 mcgm/kg/day

Protein

Actual protein requirements for the LBW infant remain uncertain. The current enteral protein recommendation is derived from in utero nitrogen accretion rates and protein composition of preterm human milk. By extrapolating fetal nitrogen accretion rates in the latter half of pregnancy and postnatal nitrogen excretion rates, 3.5 gms/kg/day of protein has been recommended.[8] Atkinson, et al, when comparing term and preterm human milk, found the protein content of preterm breast milk 20% greater for the first month of life.[9] He concluded the protein requirements are for LBW infants also 20% greater than in term infants. Heird, in a commentary discussing LBW infants' feedings, cites the "generally accepted" protein requirement in the range of 2.5 to 4 gms/kg/day.[10] The preterm formulas developed reflect the 60:40 whey:casein ratio and amino acid concentrations in term human milk. The lower protein content of term human milk differentiates it from the preterm formulas. Preterm human milk has a protein content higher than in term milk and lower than the preterm formulas.[11]

Carbohydrates

Lactose is the sugar present in human milk and most formulas. However, the LBW infant is known to have lactose intolerance and decreased intestinal lactase activity until 34-38 weeks of gestation.[11,12,13] Glucose polymers, which have replaced 40-50% of carbohydrate in preterm formulas, tend to empty the stomach more quickly than lactose or glucose feedings. These feedings also have the advantage of increased caloric density without increased osmolarity.[13]

Fat

Steatorrhea of prematurity has been attributed to decreased pancreatic lipase activity and lower bile salt production, uptake, and resorption. These mechanisms are not fully functional until 36-37 weeks gestation. This phenomenon affects mainly the absorption of long-chain fatty acids.[11,14] Premature formulas contain a mixture of medium-chain triglycerides (MCT) and long-chain triglycerides. MCT are absorbed directly into the portal vein, bypassing the bile salt deficiency. However, Okomoto, et al, demonstrated a decrease in fat malabsorption with using MCT, but no concomitant increase in growth velocity.[14] The benefit of MCT may be offset by an increased incidence of vomiting, abdominal distention, and loose stools.

Calcium and Phosphorus

Compared to in utero accretion rates, bone mineralization is delayed in LBW infants fed standard infant formula or human milk. To replicate fetal accretion rates, which rise exponentially to 38 weeks, Steichen, et al, found it necessary to provide 200-250 mg/kg/d and 100-200 mg/kg/d phosphorus.[15] Delayed bone mineralization and rickets have been observed in infants receiving vitamin D supplementation, suggesting the occurrence is usually a mineral, not a vitamin deficiency.[16] Factors that predispose LBW infants to hypocalcemia and hypophosphatedmia are soy formulas, human milk, and parenteral nutrition. These feedings all supply inadequate amounts of calcium and phosphorus. Diuretic therapy increases renal excretion of calcium in premature infants.[17]

Vitamin E

Low birth weight infants of less than 37 weeks have low vitamin E stores and variable absorption capacities.[18] In premature infants, a vitamin E deficiency syndrome, characterized by hemolytic anemia and generalized edema, has been described.[17] Hittner, et al,[19] suggests the severe retinopathy of prematurity can be reduced by therapeutic (100 mg/kg/d) vitamin E administration to infants less than 1500 grams at birth. The less severe forms of ROP were not affected and the study failed to show a decrease in incidence of ROP with vitamin E use. Johnson, et al, correlated therapeutic vitamin E serum levels (5 mg/dl) with sepsis and late onset NEC in infants less than 1500 grams birth weight, the same infants at highest risk for ROP.[20] The recommended intake of vitamin E is 25-100 IU/day. Serum vitamin E levels should be monitored and maintained between 1-3 mg/dl.[17]

Iron

In utero, the fetus accumulates iron stores at a proportional rate to its increase in body weight. A LBW infant will tend to develop iron deficiency anemia because of an abrupt decrease in red blood cell production at birth, frequent blood sampling, and inadequate dietary iron intake. The iron stores the premature infant is born with are usually depleted by three months of age. Adequate serum levels of ferritin are reported when the infants are supplemented with iron (2 mg/kg/d) starting at three weeks or two months of age.[22] Supplementation is accomplished by either iron fortified formula or an iron preparation.

Folate

Folate, an important coenzyme in many amino acid conversions, is lower in the premature infant than the full term infant. During rapid growth in

the first three months of life, there is an increase in folate requirement. The premature infant is likely to develop a folate deficiency because of these factors, and if lengthy infection, chronic diarrhea, or anticonvulsant therapy ensue. Prolonged folate deficiency will result in neutropenia, thrombocytopenia, and pancytopenia. Preventative supplementation of folic acid is 50 mcg/day.[17]

Copper

Rapid growth requirements and decreased hepatic stores of copper in prematurity make the premature infant at risk for copper deficiency. Copper deficiency is manifested by neutropenia, hypochromic anemia unresponsive to iron therapy, and osteoporosis. The deficiency can be prevented by a copper intake of 90 mcg/kg/day in the enterally fed infant. Liver dysfunction and intestinal malabsorption can increase the requirement of copper in the preterm infant.[17]

Zinc

Zinc is a crucial mineral in growth and development. Zinc deficiency significantly alters DNA replication, cell division, and nutrient metabolism. Premature infants are born with depleted stores of zinc.[22] Most formulas contain the recommended 0.5 mcg/100 kcal. However, zinc deficiency has occurred in infants with prolonged courses of parenteral nutrition and/or increased intestinal losses.[17]

Conclusion

Optimal nutrition for low birth weight infants is essential for normal growth and development. The optimal content and mode of presentation within the constraints of the infant's medical condition remains unclear.

Inadequate caloric and protein intake, vitamin, and mineral deficiencies are still common occurrences. Recognition of these deficiencies has led to development of LBW formulas with a whey:casein ratio similar to human breast milk; a mixture of lactose and glucose polymers to decrease osmolarity with increased calories and tolerance; a mixture of medium- and long-chain triglycerides as a fat source to lessen fat malabsorption; and supplemental calcium, phosphorus, iron, folate, vitamins, and minerals because of the decreased stores in the low birth weight infant and the disease states common to this population.

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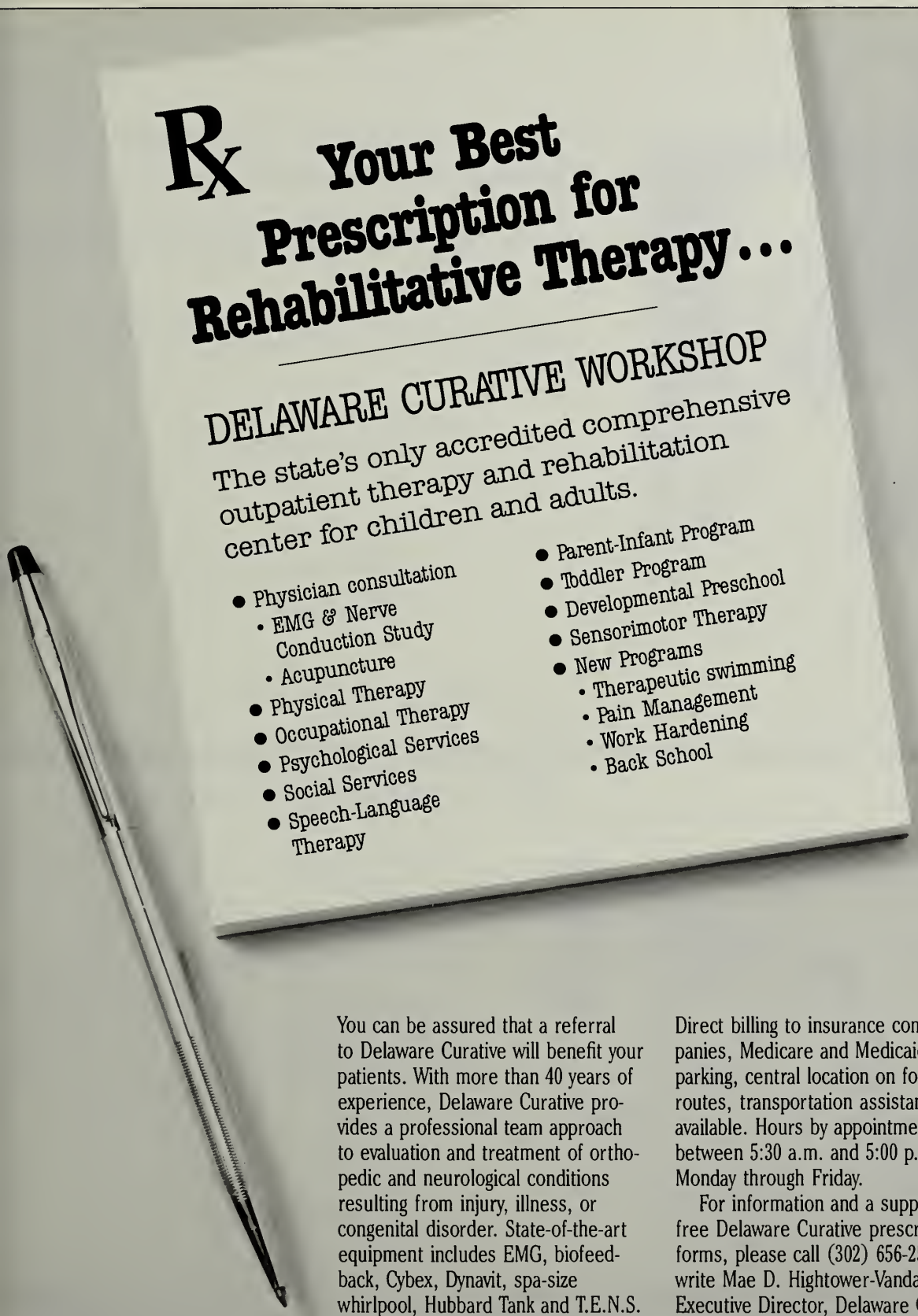

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A MULTIDISCIPLINARY APPROACH TO DEVELOPMENT DELAY IN HIGH RISK INFANTS

Nidia de Yanez, M.D.

Introduction

If parenthood presents serious challenges to adults, the same demands placed on adolescents to care for high risk babies are nothing short of monumental. Children having children (in Delaware, 42% of parents of the high risk population are age 18 and under), pose a serious threat to the future of these special babies, their families, and the community.

Recognizing the need to deal with this staggering problem prompted the organization of a multidisciplinary team of professionals and representatives from community agencies involved in the care of these infants and their families, as well as a proposal for a Parent and Infant Program for High Risk Babies at The Medical Center of Delaware.

Scope of the Problem

Recent statistics show that Delaware has the highest rate of newborn mortality in the nation and the highest non-white teen pregnancy rate. In addition, 42% of the high risk newborn intensive care unit and transitional nursery infants are born to teenage mothers; and 95% of those mothers present psychosocial and developmental problems that place them in a high risk bracket in their parenting capacity. Approximately 300 to 900 infants admitted annually to the high risk nursery have adolescent mothers with identifiable risk factors (Table 1).

Dr. de Yanez is chief of Child and Adolescent Psychiatry, a senior member of the Department of Pediatrics, and an associate member of the Department of Psychiatry at The Medical Center of Delaware.

The Multidisciplinary Approach

The first year of the multidisciplinary approach confirmed the team's awareness of the relationship between adolescent pregnancy and poverty, family dysfunctions, developmental delays and arrests, and learning disabilities. The results are high risk babies with multiple problems in need of prolonged, complicated, costly hospitalizations, and serious parenting disorders with poor bonding and attachment and developmental delays for the new generation.

The multidisciplinary team approach represents a beginning in responding to these problems. The team has a developmental approach integrating the following disciplines and services: neonatology, child psychiatry, developmental specialist, neonatology clinical specialist, social service representatives, pastoral services, protective services representatives, public health services representatives, and developmental psychology.

Recognizing the size of the task, the team identified priorities and developed a comprehensive concept. When a multi-risk infant family unit is identified, the following criteria were followed:

1. High risk mothers must be identified in the prenatal period, and in cooperation with the

perinatologist, early intervention established.

2. Assessment and recommendations are communicated to the multidisciplinary team.

3. Identification of need should be conducted by clinical specialists, social services, and nursery staff for comprehensive assessment.

4. In-depth individual and family developmental assessment should be conducted by developmental specialists, if indicated.

5. As a relationship develops, one member of the team is identified as designated communicator.

6. Review of clinical findings, systematization, and synthesis of clinical material should be performed.

7. A comprehensive coordinated follow-up program must be established.

TABLE I
PRINCIPAL MATERNAL RISK FACTORS

The American Psychiatric Association and the American Association on Mental Deficiency have identified the following factors which may lead children to having some type of developmental delay:

- Infections and Intoxication
  - Prenatal Infection
  - Rubella
  - Syphilis
  - Postnatal Cerebral Infections
  - Bacterial (i.e. post-infections encephalitis, meningitis)
  - Viral
  - Intoxications
  - Toxemia of pregnancy
  - Maternal Intoxication (drugs, poisons, exposure/industrial chem.)
  - Lead
  - Post - immunizations
- Trauma or Physical Agent
  - Prenatal injury (i.e. exposure to x-ray, mechanical injury at birth, postnatal injury - fractured skull)
- Metabolism and Nutrition
  - Lipid storage diseases (i.e. San Felippis, Hurler's disease, Tay-Sachs)
  - Amino Acid Disorder (PKU)
  - Failure to Thrive
  - Endocrine Disorder
  - Nutritional Disorders (inadequate diet, metabolic disorder, parasitism)
  - Gross Brain Disease (postnatal)
  - Unknown Prenatal Influences
  - Chromosomal Abnormality
  - Gestational Disorders
  - Small for Date (low birth weight)
  - Genetic Abnormalities
  - Convulsive Disorder
  - Phychiatric Impairment
  - Developmental Psychosexual, Cognitive, Developmental Arrests or Delays

The Need for a Follow-up Program

The work of the multidisciplinary team should be linked to a comprehensive follow-up program at its own dedicated center, such as one proposed by The Medical Center of Delaware in collaboration with the State of Delaware Department of Health and Human Services, Division of Public Health, Department of Services for Children, Youth, and Their Families, the Department of Public Instruction, and Alfred I. duPont Institute.

The Parent and Infant Program (PIP) for High Risk Babies is aimed at identifying infants at high risk for developmental delay, both physical and psychological. The goal of the program is to prevent development delay and its consequences, to help mothers to overcome their own developmental delays and arrests, and to prevent the repetition of the same pathologic systems that have often been present in those families through several generations.

For the child at risk, time is crucial. Early intervention has proved effective in minimizing the effects of atypical and/or delayed behavior while maximizing a child's growth and development in the critical early months.

PIP would provide coordinated medical and therapeutic services in a centralized way in order to improve both medical and psychosocial outcomes. The program would consist of the following components: identification of high risk babies through The Medical Center of Delaware's Pediatric Department; in-depth evaluation by the Diagnostic Assessment Team; intervention through physical therapy, speech and hearing therapy, special treatment services, and educational and recreational programs; reassessment by the Intervention Team of each child's progress; and evaluation of the Parent and Infant Program to measure its overall impact on the short term and long term. In addition, a home-based interview program is an integral part of the intervention strategy; homes are visited periodically to assist parents in improving their teaching and parenting skills with their children, and to promote nurturing. Appendix A outlines two theoretical high risk babies' case histories and probable results of intervention and treatment through the combined work of the multidisciplinary team and the Parent and Infant Program.

Standard testing instruments used during the diagnosis and intervention processes include, as appropriate: Bayley Scales of Infant Development,

the Brazelton Neonatal Behavior Assessment Inventory, the Developmental Check List, Motor/Infant Interaction Ratings of Ainsworth Bell and Staton, Watts-Mother-Child Interaction Scale, the Bayley Infant Behavior Record, Cattwell Developmental Test, Piaget's Developmental Test, Caldwell, Heider and Caplan Inventory of Home Stimulation, the Broussard Neonatal Perception Inventory, physical examination, and a mother/child interview.

Prior to PIP, an evaluation plan would be developed, including statistical techniques for measuring validity and reliability of information gathered. The evaluation plan would be based on criteria related to general development areas and developmental delays (Table 2). In addition, there are many other medical and environmental factors which should be taken into consideration for possible developmental delays. If these conditions are diagnosed as early as possible, a child can be monitored and possibly an early intervention program begun to prevent potentially more serious exceptional educational needs.

Conclusion

The first three years of life are the most critical years of a child's development, a time when the foundations of personality, physique, and character are developed. Up until now, the care of high risk babies has been left entirely to the discretion of their parents, who developmentally, are often children themselves. With the work of the multidisciplinary team, together with the proposed centralized Parent and Infant Program, Delaware is taking solid, positive steps to address the tragic waste of human life and potential, and improve the life of Delaware's most vulnerable children. Well-planned, comprehensive early intervention and treatment can and will make a difference.

TABLE 2
GENERAL DEVELOPMENT AREAS RELATED TO SIGNIFICANT DEVELOPMENT DELAYS

Significant Motor Impairment
- Nonambulatory
- Growth and/or Fine Motor Delay
- Child functions at or below 80 percent of the chronological age on standardized measure

Significant Emotional (Affective) Disorder
- Disruptive behaviors toward self and others

Significant Cognitive Deficients
- Child functioning at or below 80 percent of the chronological age on standardized measure

Significant Language Delay
- Child functioning at or below 80 percent of the chronological age on standardized measure

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Acknowledgments

From the time the multidisciplinary team was established, it has been rewarding to see the cooperative effort between the disciplines represented by team members and the value perceived by neonatology and perinatology members in integrating the comprehensive and developmental components of the project.

I want to express my appreciation for the work and devotion of the following people to this project: Katherine Esterly, M.D., Director of Neonatology, The Medical Center of Delaware, and other professionals of the Neonatology Department; members of the Multidisciplinary Team; Garrett Colmorgen, M.D., and members of the Perinatology Team; Sandy Kaplan, R.N., Pat Drake, R.N., and Pauline Lauer, for their coordinating efforts; Peggy Hollinger, for work on the proposal of the PIP; Sarah Garrison-Leo for her advice on organization of the work; and Michael L. Spear, M.D., for his interest in this work and the opportunity to participate in the Pediatrics issue of the *Delaware Medical Journal*.

APPENDIX A
HIGH-RISK BABY I

Case History: Prenatal care - 3 visits
Birth weight - 2 lbs., 4 oz.
Insurance - private
Mother's age - 17; gravida 1
Diagnosis - hyaline membrane disease, apnea, bradycardia, hypocalcemia, hypoglycemia
Marital status - single, father available

Typically (currently)
* Baby admitted to Medical Center's Neonatal Intensive Care Unit (NICU)

* Seen and monitored by neonatologist and housestaff
* Case followed weekly in nursery rounds by professional team
* At approximately 40 weeks corrected gestational age, with mother present, Brazelton test administered.
* Case reviewed and assessed periodically by Developmental Follow-up Committee based on risk factors.
* Baby referred to the care of private pediatrician for routine follow-up. Baby referred to Developmental Follow-Up Clinic at discretion of private pediatrician.
* Mother "stays home" to care for child's special needs, does not return to school to finish education.
* Compliance poor because mother fails to keep appointment.
* Baby readmitted for failure to thrive, respiratory infection or gastroenteritis (most common complaints).
* Child admitted to Emergency Room for trauma related injuries (child abuse).

In Parent Infant Program (PIP) . . . in addition

* Pediatrician discusses PIP with mother and refers case to intake worker for follow-up.
* Case assessed by Diagnostic Assessment Team; recommendation made to refer to PIP based on identification of the following problems:
  1. poor regulatory behavior (sleep and feeding problems due to hypertonicity)
  2. diminished motor processes
  3. poor mother-infant interaction
  4. poor parenting skills
* Prior to baby's discharge contact made with mother by intake worker to recruit mother and infant into program, secure informed consent, and schedule first home visit.
* Implementation of family treatment plan.
* Baby
  - weekly baby check ups through private pediatrician
  - developmental intervention
  - nutritional needs
  - mother returns to school to finish high school education
  - schedule mother at day care at least 3 hours/week when ready to work on mother/infant interaction.

  Mother/Father
  - mother works at day care at least 3 hours/week not to interfere with school
  - mother and father participate in parent training program
  - family participates in family therapy (short term)
* Treatment plan assessed weekly with input from all available resources.
* Treatment continues until:
  1. baby reaches age-appropriate stages of development
  2. shows no signs of physical or emotional problems
  3. mother's skills and insights related to her baby's specific handicap(s) have reached acceptable level
* Discharge or referral to Head Start.

HIGH-RISK BABY II

Case History: Prenatal care - 2 visits
Birth weight - 1 lb., 6 oz. (620 grams) (small for gestational age)
Insurance - none
Mother's age - 25; gravida 3, 2 abortions
Diagnosis - severe prematurity; retinopathy
Pregnancy history - mother is a prisoner finishing prison term (1 year) with history of alcohol and drug abuse prior to incarceration; heavy smoker; vaginal bleeding with premature labor
Marital status—single, father not available

Typically (currently)

* Baby admitted to Medical Center's Neonatal Intensive Care Unit (NICU).
* Seen and monitored by neonatologist and housestaff; mother and infant treated for withdrawal.
* Case followed weekly in nursery rounds by professional team; social worker assigned to case for foster care placement.
* Mother returns to prison following her recovery.
* At approximately 40 weeks corrected gestational age, Brazelton test administered.
* Case reviewed and assessed periodically by Developmental Follow-up Committee based on risk factors. Protective Services involved in decision making.
* Prior to discharge foster mother receives training on home monitoring because of abnormal pneumogram.
* Prior to discharge the neonatologist refers baby to the Developmental Follow-up Clinic.
* Mother released from prison shortly after baby's discharge from hospital.
* Baby returned to mother.
* Baby readmitted because of failure to thrive.
* Frequent Emergency Room visits for trauma

related injuries (child abuse).
* Mother resumes substance abuse.

In Parent Infant Program (PIP) . . . in addition
* Pediatrician discusses PIP with mother and foster mother; refers case to intake worker for follow-up.
* Case assessed by Diagnostic Assessment Team; recommendation made to refer to PIP based on identification of the following problems:
  1. no mother/infant interaction
  2. need for home monitoring
  3. functioning at below corrected age in motor processes
  4. diminished visual acuity
  5. poor family pathology
  6. volunteer advocate
* PIP day care delayed until mother assumes responsibility for baby. Protective Services recommend PIP participation when child is returned to mother's care.
* Prior to discharge contact made with mother and foster mother by intake worker to recruitment into program, secure informed consent, and schedule first home visit. Mother referrred for counseling within the Corrections system.
* Implementation of treatment plan; focus on family pathology including separation anxiety of mother.
* Case monitored by Protective Services.
* Mother participates in Parenting Classes and works at PIP 5 hours day/week. Able to seek employment.
* Treatment plan assessed weekly with input from all available resources.
* Treatment continues until:
  1. baby reaches age-appropriate stages of development
  2. shows no signs of physical or emotional problems
  3. mother's skills and insights related to her baby's specific handicap(s) have reached accepted level
  4. no evidence of adjustment problems following reuniting with mother.
* Discharge or referral to Head Start.

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MANAGEMENT OF CLOSED HEAD INJURIES IN CHILDREN

Michael Alexander, M.D.

Each year, children under 15 years of age account for 100,000 closed head injury admissions in the United States.[1] Great strides have been made in the initial care of all age groups, including regional trauma centers, intracranial pressure monitoring, phenobarbital coma, and hyperventilation with respiratory assistance. As a consequence of these new and aggressive therapies, rehabilitation of patients with closed head injuries is one of the fastest growing areas of rehabilitation medicine in the country. This is the case not only in the acute rehabilitation setting, but also in the development of long term residential facilities to care for patients with more severe, persisting problems.

Studies have described phases of recovery that patients with head injuries experience.[2,3] These usually begin with the patient gradually regaining consciousness and experiencing agitation, progressing to a nonpurposeful confusion, and continuing as the patient begins to show some alertness and orientation to surroundings. As the patient continues to recover, a more concrete stage is entered in which the child does not do well with abstract concepts. After this, the patient experiences what is described as "automatic appropriate stage," which particularly refers to activities that are well learned and occur in social situations where the patient has previous experience. However, if the patient is placed into new and challenging situations, difficulties are experienced.

In the early phases of the recovery process, the child with closed head injury usually suffers from severe associated medical problems, and the central nervous system is so unstable that nursing procedures and simple positioning can cause alarming swings in intracranial pressure. When the child is stabilized medically, rehabilitative therapeutic interventions can begin. Most children show their most dramatic and rapid improvement in the first six months after closed head injury. At this time, it is appropriate to transfer the injured child to a facility where the initial acute rehabilitation phase can be managed.

In the beginning phases of rehabilitation, attention is turned to feeding, reestablishment of bowel and bladder continence, and maintenance of skin integrity. Nursing personnel are responsible for frequent turning and repositioning of the child to prevent tissue breakdown. Pulmonary toilet by positioning and drainage becomes important because in the early phases after injury the cough reflex may not have returned fully.

Feeding requires careful attention to determine whether the patient aspirates when swallowing. Initially, the patient who cannot swallow food is managed with a nasogastric tube with later conversion to a gastrostomy if necessary. When the patient is receiving adequate caloric intake through a feeding tube, a speech pathologist or an occupational therapist is able to start a feeding rehabilitation program with the child. The therapist can foster the practice and development of a more suitable eating pattern by the use of facilitatory techniques and by enlisting the assistance of other professionals for placing the child in the optimal seating position for feeding. The feeding program begins with clear liquids, progresses to chopped foods, and advances to a regular diet. Abnormal oral reflexes are identified and neutralized, or techniques are used that allow progression of the feeding program in spite of their persistence.

Dr. Alexander is chief of the Division of Rehabilitation at Alfred I. duPont Institute in Wilmington, Delaware.

In the early stages of rehabilitation, all efforts are aimed at maximizing and focusing sensory input and helping the patient establish contact with familiar aspects of life. The presence of family members and close friends is important. Families are encouraged to bring in the child's favorite toys, blankets, and pictures, and the child is placed in a more routine program in an attempt to reproduce home regularity. As the child awakens and begins to show some response but remains in a confused state, he needs constant reminding of the setting and why he is there. The younger the child, the simpler these reassurances need to be, but even the youngest child needs to be calmed and reminded that he is safe.

Occasionally, a child coming out of the agitated stage may behave inappropriately due to stress created by numerous personnel present in the room. It is most appropriate for these patients to have only one treating therapist present and as few nurses as possible. When the patient reaches the alert, concrete stage, he may be ready to be discharged from the hospital and placed in a comprehensive outpatient program. The two principal rehabilitation goals at that time are to help the patient achieve maximal function recovery, and to help the patient cope with any permanent residual disabilities. This necessitates involvement of the family in the rehabilitation process so they can learn what to expect during the child's recovery.

It is important that the care of these children occur in an integrated and coordinated fashion. The physiatrist must consider input of multiple disciplines (i.e., physical and occupational therapy, speech pathology, rehabilitation engineering), and identify the necessary components for a particular patient's rehabilitation program. This is more easily accomplished in specialized rehabilitation centers and units. It has been noted that the usual hospital setting may aggravate the patient's perceived isolation and cause a form of sensory deprivation on a nervous system already having difficulty interacting with the environment. The need for sensory stimulation is recognized as an important factor in the eventual outcome of head-injured patients; the activities of concentrated stimulation during the day have benefits in improved sleeping and nighttime behaviors, and simulation of a daily regimen of normal, routine activities will minimize the confused state and allow the patient to show maximal capabilities.

When working with the child passing through the levels of cognitive recovery, one of the principal goals must be to prevent deformities and complications of the underlying insult. Prevention of deformity begins in the intensive care unit with positioning and appropriate splinting. As soon as it is tolerable, the child can be placed in a seated position that will optimize alignment of the hips and knees, will further minimize tone, and will facilitate more normal motor function. In patients with closed head injury, spasticity can result in development of contractures and uncontrollable spasms that can interfere with sitting and other activities. A number of techniques are used by both the therapist and the physician in order to help minimize these problems. Preferential excitation of muscle spindles through stroking, vibration, and icing produces reflex contracture in the treated muscle and reciprocally can inhibit motor neurons in the antagonistic muscles. Once there is a reduction in spasticity, the therapist can proceed with more traditional exercises to help the child experience control of those groups of muscles. Inhibitory casts and boots, inhibitory positions, and neurodevelopmental positions all may facilitate the patient's ability to regain control of a particular muscle group. Biofeedback has been shown to be effective in some individuals and may help them discover muscle groups that have been inhibited by the overactivity of their antagonistically spastic muscles.

Spasticity management also includes systemic and locally injected drugs. The systemic drugs fall into two broad categories: drugs such as diazepam and baclofen, which are essentially polysynaptic inhibitors; and drugs including dantrolene sodium, which unlike the polysynaptic drugs, affect muscles directly, appearing to block calcium influx from the "T" system of the muscle fiber. Dantrolene sodium has been shown to be effective in the management of spasticity in children and can be used in relatively low doses. Pharmacologic agents such as phenol and alcohol can be injected directly into nerves or motor points of muscles, thus decreasing spasticity. These injections wear off with time; by then, the child may have had further recovery of brain function and be able to use the extremity more functionally.

In those children whose persistent motor control problems impair language, but who cognitively are to the point at which they could talk, augmentative communicative devices with talking chip components should be provided.

Children with head injuries can develop medical complications that require a specific intervention. Older children can develop thrombophlebitis, and are also prone to heterotopic ossification that results in periarticular calcium deposits that interfere with or eliminate range of motion. Alkaline phosphatase level will be greatly elevated and bone scanning will show abnormal activity in the area. Such areas should not be surgically

resected until all new bone formation has ceased. In the early phases of immobilization, these children can show hypercalcemia, which presents as nausea, vomiting, hypertension, and renal calcification. The hallmarks of treatment are high fluid intake, low calcium intake, acidification of the urine, and passive and active exercise.[4] Calcitonin has been shown to be effective by some authors,[5] but the most effective form of treatment remains rapid mobilization of the patient.

A sudden appearance of decreasing range of motion, shiny skin, hair loss, and pain in the extremity heralds sympathetic dystrophy. This autonomic dysfunction requires therapeutic intervention, including contrast baths, paraffin, pneumatic compression, and transcutaneous neural stimulation. More severe cases will respond to ganglionectomies and tapered steroid administration.

The majority of children with closed head injuries are able to walk out of the hospital and dress and care for themselves. However, what is commonly deemed a "normal" outcome is often less than satisfactory. Some studies have shown only a 17% good outcome in patients who are comatose longer than four weeks, "good" being defined as returning to school or work at a level comparable to that prior to injury in terms of behavioral or mental abilities.[6]

Patients with prolonged posttraumatic amnesia show poor performance upon returning to work, and impaired school capabilities. Although some studies show high numbers of patients returning to work, it is often demonstrated that these patients do so by having downgraded jobs or positions that require less public interaction. Although post-injury ambulation ability correlates well with independence and activities of daily living, it does not correlate with persistent psychological and educational outcome. Two studies show that from 33 to 66% of children with closed head injuries and in a coma of more than six days, at best have problems in school.[7,8] Rayes looked at how patients awoke and found that 83% of patients who were agitated on awakening have a good outcome, compared with only 19% of the sluggish reactors.[9] However, patients still agitated at the time of discharge showed the highest incidence of psychiatric problems. In predicting outcome and complication, it has been found that patients who have more sensory than motor signs eventually do better, as do patients with more normal evoked brain potentials. Intracranial hematoma and late onset seizures correlate with a poor outcome. Certainly, patients with a low IQ prior to injury do worse, as they appear to have more problems from wider memory defects affecting perception and immediate recall. Hemiparesis is more likely to be associated with severe intellectual declines. As many as 30% of children with closed head injuries are likely to show behavioral and personality changes.

Posttraumatic epilepsy in children with closed head injury ranges from 5 to 9% and is more common in patients with open injuries and focal deficits. Posttraumatic syndrome in children is not like the adult pattern of vertigo and headaches, for as many as 50% of those adult patients with severe head trauma have subjective symptoms of dizziness and disequilibrium upon objective electronystagmography. The most common, persistent problem after closed head injury in children, which for the most part has shown good recovery, is decreased ability in visual perception and in rapid decision making. These children have difficulty altering their thinking as quickly as before and seem more overwhelmed by having to sort out multiple stimuli.

When medically stable and transferred to an appropriate rehabilitation center, children with closed head injuries have a high likelihood of becoming ambulatory and independent in daily living activities. Through careful psychological and educational support, they have the best chance of returning to their preinjury educational activities. These patients will probably have persistent learning disabilities since they are not like children with a classic minimum brain dysfunction or learning disorder, as they persist in having more difficulties with visual spatial skills and activities that require rapidity. Finally, their need for rehabilitation will persist until they finish school and are able to train for a vocation.

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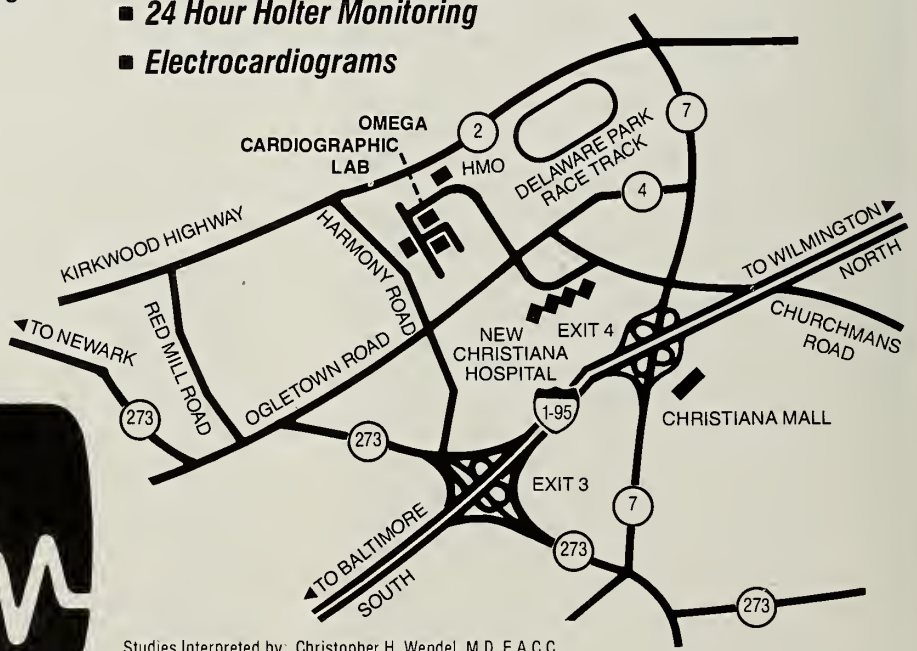

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PEDIATRIC ONCOLOGY—THE TEAM APPROACH AT THE MEDICAL CENTER OF DELAWARE

Rita S. Meek, M.D.

Introduction

Great strides have been made in childhood cancer over the past 25 years. Now, well over half of all children with malignancies will be cured of their leukemias or solid tumors. Some children with Wilms' tumor or good risk acute lymphocytic leukemia have a 90% chance of probable cure. The development of multimodality therapy-chemotherapy, radiation therapy, and surgery-as well as the ability to provide more intensive supportive care to the child undergoing this aggressive therapy, has resulted in markedly improved survival rates.

There are several multi-institutional pediatric groups which study childhood malignancies: the Children's Cancer Study Group (CCSG), Pediatric Oncology Group (POG), and the National Institutes of Health Pediatric Oncology Branch. These groups sponsor clinical research studies which ask basic questions about various pediatric leukemias and solid tumors. Their protocols address issues ranging from prognostic features at the time of presentation to various therapeutic questions. Studies may be designed to consider various combinations and dosages of drugs, radiation therapy fields, surgical options, or possible long-term side effects of the treatment. The Medical Center of Delaware participates in CCSG through our affiliate status with Children's Hospital of Philadelphia. The institutional review board of The Medical Center of Delaware must approve each CCSG-sponsored protocol before a Medical Center of Delaware patient can participate.

When a child is diagnosed with a malignancy, the parents are encouraged to allow the child to participate in these ongoing clinical research trials if one is available for the child's particular illness. This affords the child access to the presumed best treatment which is currently available, as well as allowing each child to make a significant contribution to our knowledge about childhood cancer. Frequently, two or more promising treatments are compared. These treatment arms may differ regarding drugs, dosage, or duration of treatment. The parents may be asked to allow the child to be randomized between the different therapeutic arms. As the data is collected from the member institutions and analyzed, it may become apparent that one treatment arm is clearly superior or clearly inferior to the others. Adjustments in treatment will be made, if possible, for the children who are affected by this information. The next generation of protocols will incorporate the new data derived from the current studies into study design, and will address other therapeutic questions.

As more children survive childhood cancer, physicians who care for children with malignancies are becoming aware of the various potential late effects of treatment. Infertility, disorders

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of growth, learning disabilities, pulmonary and cardiac toxicities, thyroid dysfunction, and second malignant neoplasms are among the problems seen in long-term survivors of childhood cancer. As pediatric oncologists have become increasingly aware of the potential late effects, protocol design has tried to emphasize stratification of patients into various treatments so that minimum therapy can be delivered to a child who is likely to do well and more aggressive therapy can be delivered to the child who is more likely to succumb to his malignancy.

Pediatric Oncology Team

The goal of pediatric oncologic treatment is to have a child who is cured of his malignancy and is psychologically and physically healthy and, therefore, able to lead an independent normal life. This requires the expertise of many health care providers due to the patient's aggressive treatment, frequent severe complications of the treatment, and the psychosocial stresses imposed on the family.

The pediatric oncology team is composed of medical and nursing professionals, psychosocial professionals, and the parents. The involvement and participation of the parents and other significant family members is an integral part of the team approach to childhood cancer. The parents become extremely knowledgeable about their child's illness and its complications. They are taught to become careful observers of physical signs and symptoms so that subtle changes in their child's wellbeing can be quickly reported to medical personnel. The parents frequently learn to care for indwelling venous access devices which are placed for ease of blood drawing as well as for reliable access for antibiotics, hyperalimentation, and blood products. These catheters stay in place after the child is discharged, and the parents are generally responsible for its care while the child is at home. The parents are also taught to administer oral medications and are occasionally given the responsibility of administering intravenous medications when an indwelling venous access device is in place.

Most parents want to be extremely supportive of their child with cancer. Therefore, major adjustments must be made in the parents' working schedules to accommodate unplanned physician office visits as well as unexpected hospitalizations. Most parents want to stay with their children whenever they are hospitalized, and at The Medical Center of Delaware, they are allowed to do so. Obviously, this may cause a serious conflict for parents who are employed or have other children to take care of.

When a child is able to return to school, the parents may need to assume the role of educator. The parents may need to educate school personnel about their child's malignancy and what limitations are necessary on his activity. Most school personnel have had only a limited exposure to children with cancer and often look to the parents to provide information and support for the school staff. The parents often act as the liaison between the school and the medical personnel.

The medical care of the child with cancer is usually coordinated by a physician skilled in dealing with children with malignancies. For many years, Delaware children with leukemia have received excellent care locally under the direction of the adult hematologists. The Medical Center of Delaware became an affiliate in CCSG through their efforts. Only under unusual circumstances has a child with leukemia needed to go outside Wilmington for medical treatment.

Children with solid tumors were, in general, sent to Philadelphia or Baltimore for definitive treatment. Now, with the recent arrival in Delaware of a pediatric oncologist, most children with malignancies are able to receive all their care locally. As additional pediatric and surgical subspecialists arrive in Wilmington, even more services can be provided locally and will further decrease the number of children who need to be referred to other centers.

Although the pediatric oncologist or hematologist generally decides on the specific treatment plan, the other members of the team are crucial--the surgeon, radiotherapist, pediatric subspecialist, pediatric nurses, and pediatric house staff. Additionally, a superb hospital must be available to provide pediatric nursing units including a pediatric intensive care unit, a blood bank which can provide 24 hour a day blood products, clinical laboratories which can provide chemistry, bacteriology, hematology, pathology, and serology determinations, and a state-of-the-art imaging facility.

The pediatric nurses who have been specially trained in aspects of pediatric hematology-oncology provide extensive teaching to the family while the child is an in-patient. They instruct the parents in care of the indwelling venous access device and are able to discuss the various chemotherapeutic agents that the child is receiving and the expected toxicities. Frequently, when the child goes home, the visiting nurses from the community are involved in evaluating the patient on a home visit basis. Also, home health care nurses can be involved in supervising the administration of hyperalimentation while the child is at home.

Psychosocial Support

The diagnosis of cancer in a child can cause an

overwhelming stress for a family. Social workers help with insurance and other economic issues; they also offer ongoing support for the family. Additionally, The Medical Center of Delaware has a parent liaison coordinator who meets with the parents and the child with cancer in an ongoing fashion to attempt to avoid significant psychosocial problems which may develop during the course of the illness. A night time support group for parents of children with a chronic illness is also led by the parent liaison coordinator. The family or child are encouraged to meet with a psychologist or psychiatrist if this appears necessary.

When a child is hospitalized, the educational coordinator, in conjunction with the child's regular school teacher, provides appropriate material for the child in an onsite classroom on the pediatric floor or in the child's hospital room. When the child is ready to be discharged, the educational coordinator may arrange for homebound tutoring, or may help the child's regular teacher integrate the child back into the classroom on a part time or full time basis.

Going to school is the normal daytime activity for children, and the child with cancer is encouraged to be as normal as possible. Participation in school is encouraged to whatever degree is reasonable: full time, part time, homebound tutoring, or The Medical Center of Delaware First State School for adolescents with chronic illnesses. The Adolescent Day Program is an accredited New Castle County School program which provides regular schooling for adolescents with significant, chronic medical problems who need ongoing medical attention which might interfere with their ability to remain in a regular school environment on a full time basis. The children come to the Adolescent Unit of The Medical Center and attend school there with an accredited school teacher. They also receive support from peers who have significant medical problems, and are able to participate in scheduled group therapy and family therapy sessions with an adolescent psychologist. Many of their medical needs can be addressed while they are attending the school day program.

During hospitalization, many children benefit from involvement with the Child Life Department which provides play therapy to help children deal with their anxieties. This takes place in an activity-filled playroom which is off limits for any medical procedures.

Unfortunately, not all children with cancer are cured of their malignancies. If there is a recurrence and progression of disease despite all therapeutic measures, the parents may choose to care for their child at home during the terminal phase of the illness. If the child is able, he may actively participate in this decision to begin palliative therapy which is designed to control symptoms and maximize quality of life. In this situation, the parents may benefit from the support of Delaware Hospice, a state-wide, non-profit organization which assists families who are providing terminal care at home. Pediatric patients are now eligible for the services and support of Delaware Hospice. Although the vast majority of adult patients in Delaware Hospice have cancer, pediatric patients may have a chromosomal abnormality, a life-threatening congenital defect, or an acquired illness other than cancer.

Hospice care is also delivered through a team approach. The child's medical physician generally manages the medical problems; hospice physicians are available if necessary. The nurses make scheduled home visits as often as necessary and are available 24 hours a day for crisis intervention. If a problem arises, the nurses contact the patient's physician and treatment plans are arranged, including hospitalization if necessary. Psychosocial workers can be involved with the patient, parents, and siblings, and offer assistance in dealing with the impending death. Pastoral care can be provided through the patient's own religious affiliation or through the clergy associated with Delaware Hospice. Volunteers are available to stay with the patient so the family can attend to other obligations such as work, errands, or an occasional day trip. In New Castle County, Delaware Hospice has a teenage volunteer program to provide support for adolescents and children who are patients, or children or grandchildren of patients in Delaware Hospice. Interested high school juniors and seniors participate in a four-part training program to provide them with the skills necessary for this type of work. After the death of the patient, bereavement support is avilable for the family for at least one year. If necessary, the family can be referred to other psychology or psychiatric services in the community.

Different stages in the disease process require involvement of various members of the team. All members are not actively involved at any one time, and no child needs the services of every potential member of the team. When the child is doing well in his treatment regimen, relatively few health care professionals are involved. However, the time of diagnosis, return to school for the first time, first relapse of the disease, and the terminal phase of the illness all require the involvement of many different individuals.

For illustrative purposes, two hypothetical case histories follow. Although hypothetical, they provide a realistic view of the complicated multi-

factorial aspects of pediatric oncology care as it is currently provided at The Medical Center of Delaware.

Case 1

A.B. was a five year old white male seen by his private pediatrician in Dover, Delaware, for bloody urine. Hypertension was noted; an abdominal mass was palpated. A.B. was referred to The Medical Center of Delaware for further evaluation. The patient was seen by a pediatric surgeon who felt that the most likely diagnosis was an abdominal tumor. A pediatric oncologist was consulted and a CT scan of the abdomen, pelvis, and chest were performed. These films were reviewed with the pediatric radiologist; the most likely diagnosis was felt to be a Wilms' tumor of the right kidney. A pediatric nephrologist was involved in the preoperative management of the hypertension. Prior to surgery, A.B. and his parents attended a surgical teaching class which included a slide presentation designed for pediatric patients, and the family went on a tour of the operating area. The parent liaison coordinator met with the family to offer support; a pediatric social worker made a referral to the American Cancer Society and encouraged the parents to become members of the Blood Bank of Delaware. A hospital chaplain visited frequently with the family.

An exploratory laparotomy was performed; the general anesthesia was administered by a pediatric anesthesiologist. A Stage I, favorable histology Wilms' tumor was resected. Post-operatively, A.B. was registered on the National Wilms' Tumor Study IV and was randomized to receive 18 weeks of chemotherapy. No radiation therapy was felt to be necessary. He began his first five-day course of vincristine and Actinomycin-D on the sixth post-operative day. During A.B.'s hospitalization, the child life workers provided A.B. with play therapy sessions to help him cope with his anxiety over his unexpected hospitalization and surgery. A.B.'s parents received extensive teaching and support from the nurses, the pediatric oncologist, and the parent liaison coordinator. They were given literature about the tumor, as well as information about the stresses this illness could place on their family. During A.B.'s hospitalization, his parents were invited to participate in an ongoing parent support group which met monthly in the evenings for parents of children with chronic medical conditions. Due to financial restraints, A.B.'s father returned to work after several days, and A.B.'s mother remained with him at The Medical Center of Delaware. His father came nightly to see A.B. and brought A.B.'s eight year old brother to see him on the weekend. A.B. tolerated his chemotherapy well and was discharged on the tenth post-operative day.

He returned weekly to Wilmington for blood work and out-patient chemotherapy. After five weeks of chemotherapy he developed symptoms of an upper respiratory tract infection. He was seen in Dover by his own pediatrician. On physical examination, he was nontoxic appearing and afebrile. His abdominal surgical scar was well-healed; an otitis media was noted. CBC showed WBC of 4,500 with 50% segmented forms; therefore, his absolute neutrophil count (ANC) was 2250 [ANC = (segs + bands) x WBC x .01]. A telephone consultation between the pediatrician and the pediatric oncologist occurred. It was recommended that A.B. be placed on oral antibiotics and seen in follow-up by his pediatrician over the next several days. He continued to do well and was not hospitalized.

However, one week after his next course of actinomycin-D, he was noted to be febrile to 103°F and lethargic. He was normotensive and well perfused when he was seen by his pediatrician. His CBC showed a WBC of 200 with no segmented forms (ANC = 0). Again, a telephone consultation occurred between the pediatrician and the pediatric oncologist. A.B. needed to be hospitalized; his pediatrician felt comfortable managing this problem in Dover. Therefore, A.B. was admitted to Kent General Hospital and started on broad spectrum antibiotics after appropriate cultures were obtained. Daily telephone contact between the pediatrician and the pediatric oncologist continued throughout A.B.'s hospitalization. He defervesced after 48 hours of antibiotics. All cultures were negative. However, his WBC remained extremely low for the next week, so his antibiotics were continued. When his ANC was greater than 500 for two consecutive days, his antibiotics were discontinued and he was observed for an additional 24 hours in the hospital. He continued to be afebrile and was discharged.

He continued his proposed regimen of chemotherapy without any major problems. Follow-up chest x-rays, abdominal ultrasound exams, urinalysis, and periodic CT scans showed no evidence of recurrent disease. He completed his planned chemotherapy as scheduled. He returned to Wilmington for follow-up, but these visits became less frequent with time. A. B. is currently four years post-diagnosis of his Wilms' tumor. He returns to Wilmington yearly to see his oncologist for follow-up of possible late effects of his cancer treatment. He continues to see his pediatrician for routine well child care. He is doing well in school and appears to be a happy, well-adjusted nine year old boy.

Case 2

C.D. was a 14 year old white female who was noted to have a lump in her neck which did not respond to antibiotic therapy. She was referred by her pediatrician to a pediatric ENT surgeon who biopsied the mass. The pathological diagnosis was an embryonal rhabdomyosarcoma; tumor was noted to be present at the margins of the excision. She was seen in consultation by a pediatric oncologist. Further workup, including a CT scan of her neck and chest, as well as bone scan and bone marrow aspirates and biopsies, revealed no evidence of metastatic disease. However, the tumor was noted to be surrounding several major blood vessels in her neck, and was felt to be nonresectable at that time. The radiotherapist recommended radiation therapy in conjunction with chemotherapy. An indwelling venous access device was placed by the pediatric surgeon for ease of chemotherapy administration as well as for phlebotomy purposes. She was entered on the national Intergroup Rhabdomyosarcoma Study III.

The parent liaison coordinator met individually with C.D. and with her parents. The family's pastor made frequent visits to the hospital. While her chemotherapy was being administered, C.D. received support from the nurses on the adolescent unit as well as the doctors, parent liaison coordinator, and the social worker. She met with The Medical Center of Delaware's school teacher who coordinated her schooling needs with her regular school. Because multiple complications were expected from her intensive chemotherapy and radiation treatments, it was felt that C.D.'s regular ninth grade schooling would probably be disrupted for significant periods of time. Therefore, she was enrolled in the First State School on the adolescent unit of The Medical Center of Delaware. She was able to gain support from other students who also had chronic medical conditions; she particularly enjoyed meeting with the psychologist who participated in this program. Additionally, she was able to receive most of her chemotherapy while she was in school; her radiation therapy appointments were coordinated with her school day breaks. Her oncologist saw her at least weekly during school hours so extra medical visits were minimized. Her weekly blood work was drawn from her venous access device by the nurses in the Adolescent Day Program. Blood products, such as platelets for severe thrombocytopenia secondary to her chemotherapy, were delivered during her routine school day.

As was expected, she had multiple episodes of neutropenia and fever which necessitated hospitalization for treatment with parenteral antibiotics. During her radiation therapy, she developed severe mucostitis and was unable to eat. Hyperalimentation was begun through her central line. After discharge from the hospital, she was able to receive hyperalimentation at home under the supervision of home health care nurses and the hyperalimentation service of The Medical Center of Delaware.

C.D. finished her radiation therapy and continued on her scheduled chemotherapy plan for approximately nine months. At that time a routine chest x-ray showed multiple bilateral pulmonary metastases. Both radiation therapy to her lungs and new chemotherapeutic agents were used. Unfortunately, only a brief remission was obtained. At that time, experimental regimens were attempted; her pulmonary metastases persisted. It became obvious to C.D., her parents, and the staff that the new therapies were unsuccessful. C.D. decided that she wanted to go home and receive palliative treatment. Multiple discussions were held between C.D., her parents, the pediatric oncologist, and the parent liaison coordinator. At this point Delaware Hospice was consulted. They met with the family and C.D., and spoke extensively with C.D.'s oncologist. After the assessment was completed, Delaware Hospice arranged for a hospital bed, an oxygen tank, and continuous pain medication through C.D.'s indwelling catheter. After C.D. went home, her mother provided the majority of her care. However, when her mother needed to be out of the house to run errands, Delaware Hospice volunteers were able to stay with C.D. Also, a Delaware Hospice teenage volunteer from one of the local high schools visited C.D. several times a week and called her frequently to chat. The Delaware Hospice nurses made frequent home visits and conferred with C.D.'s oncologist to adjust her pain medication to keep her comfortable. The oncologist provided new prescriptions and other medications as they became necessary. Over several weeks, C.D. became increasingly dyspneic. Delaware Hospice nurses, volunteers, and social workers make daily home visits to support the family and to help keep C.D. as comfortable as possible. C.D. suffered a respiratory arrest at home surrounded by her parents and siblings. Her physician made a home visit to pronounce her death. Her family's pastor presided at her funeral service. Many representatives from The Medical Center of Delaware and Delaware Hospice joined C.D.'s friends and family at the funeral service. For one year after C.D.'s death, bereavement support was provided for her parents and siblings through Delaware Hospice. Additionally, her parents became active participants in a bereaved parents support group at The Medical Center of Delaware which was facilitated by the

parent liaison coordinator. It is now three years after C.D.'s death; although her family still misses her and talks about her frequently, her parents and her siblings appear to be coping well and are involved in normal activities.

Future Directions

There are several programs which are being considered to expand and improve services which are available for the pediatric oncology patient at The Medical Center of Delaware. Some of these follow.

A pediatric tumor board may be developed to include the expertise of the oncologist, radiation therapist, surgeon, and pathologist. Additionally, various subspecialties would be invited to participate in management discussions regarding a particular patient. This would provide a mechanism for review and discussion of each child with a malignancy.

It is hoped that an expanded solid tumor service will allow more children to be treated for their malignancies within the state of Delaware. With the addition to our community of another pediatric surgeon, as well as additional pediatric subspecialists, the ability of The Medical Center of Delaware to provide superb care for these children will continue to expand.

Bone marrow transplantation will soon be offered in the adult hematology and oncology services; autologous bone marrow transplants will be used in the initial phase. Perhaps this program will ultimately expand into the pediatric age group.

Outreach into the community will be attempted. Various possibilities include an inservice program for school nurses and teachers throughout the state so that they can become more knowledgeable about medical aspects of the child with cancer. A pediatric nurse who is specially trained in pediatric oncology might be used to go through the various schools when a child is diagnosed with cancer and provide inservice to the students, the child's teachers, and the other administrative personnel who are involved with the child so that they can better understand the individual child's medical problems and how best to reintegrate him into the classroom.

Plans are underway to develop a sibling support group to provide an opportunity for siblings of children with cancer or other chronic illnesses to share their feelings and experiences with other young people who are in similar circumstances.

A Ronald McDonald House will be available in Delaware within the next several years to provide a home away from home for families who have a child with a serious medical illness. It will be located on the grounds of the Emily Bissell Hospital and will serve both the Alfred I. duPont Institute and The Medical Center of Delaware. The Ronald McDonald House will provide families with the opportunity to stay in a warm, home-like environment while their child is undergoing medical care at one of these facilities. The families would then be able to derive support from meeting others staying at the Ronald McDonald House who are also going through similar medical circumstances.

Summary

The Medical Center of Delaware can provide excellent pediatric oncology care for children with a variety of malignancies. Our affiliation with the Children's Cancer Study Group, and our ability to involve multiple, well-trained health care professionals allows delivery of state-of-the-art cancer treatment. As new therapeutic modalities become available, they will be incorporated into our expanding program.

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*These citations refer to the Principles of Medical Ethics which may be found in the rear of the 1987-1988 Pictorial Roster of the Medical Society of Delaware

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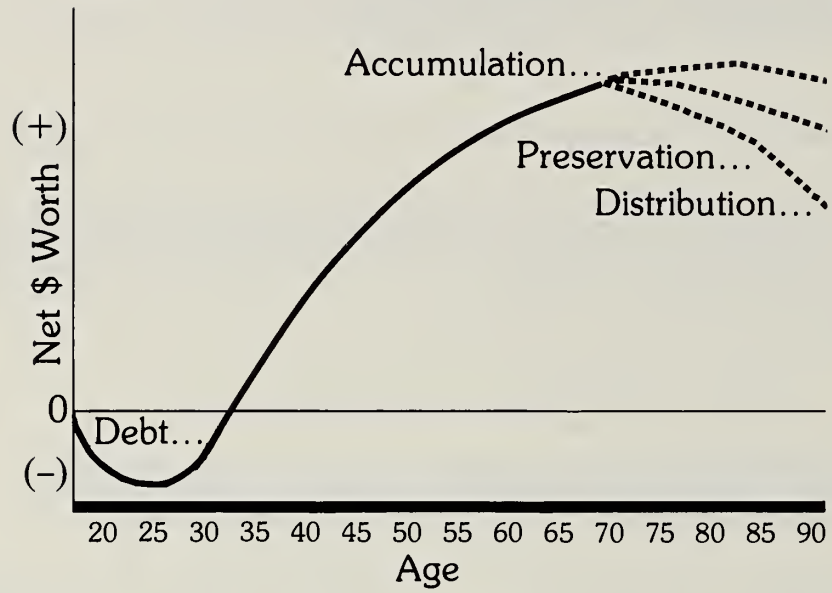

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Editorials

SPOTLIGHT ON THE GUEST EDITOR

Dr. Michael L. Spear has been an attending neonatologist in the Division of Neonatology, Department of Pediatrics at The Medical Center of Delaware since 1984. He is also an assistant professor of Pediatrics at Jefferson Medical College. Dr. Spear graduated from Albert Einstein College of Medicine in New York and completed his pediatric residency and fellowship in neonatal-perinatal medicine at The Children's Hospital of Philadelphia. He has published several research articles on intravenous lipid tolerance in the premature infant and changes in lactation in the immediate post-partum period.

THE EVOLUTION OF PEDIATRICS IN DELAWARE

This all-pediatric issue of the *Delaware Medical Journal* illustrates the breadth and depth of pediatrics in the state of Delaware today, but also forecasts exciting new changes for the future.

The contributing authors describe the developing centers of excellence in this community. Foremost is the role of the community pediatrician; Dr. Liebesman's discussion provides an interesting perspective in this regard. In addition, Mrs. Levitt provides a nursing viewpoint regarding the rapid changes taking place in pediatric nursing. Without the sound foundation of primary care pediatrics throughout the state, the development of specialty areas of expertise would not be possible.

As the reader will discover, Delaware has multiple resources for pediatric care. Five general hospitals throughout the state provide primary pediatric care within their own communities. The Medical Center of Delaware will continue to serve as a secondary and tertiary acute care pediatric center. Within the Pediatric Department at The Medical Center of Delaware, special programs of excellence have been developed, including care of the critically ill newborn, developmental follow-up of the high-risk newborn, genetics, pediatric intensive care with particular emphasis on surgical emergencies and trauma, pediatric emergency care, adolescent medicine, and childhood cancer. These programs have been strengthened by the addition of new pediatric specialists in anesthesia, surgery, and the creation of two separate Center-based outpatient programs for adolescents with chronic medical/surgical and psychiatric illness. Soon to be launched is the Child Development Watch program for infants at risk for developmental

handicaps. Drs. Norman, Meek, and de Yanez describe some of these programs in an attempt to illustrate how The Medical Center plans to expand its services to Delaware children.

It must be pointed out, however, that there are other important areas of pediatric expertise that have been or will be developed to round out a total program for pediatric care in Delaware. In this regard, the recent expansion of the Alfred I. duPont Institute is an exciting one. Drs. Doughty and Alexander describe the growth of programs in rehabilitative medicine and rheumatology at the Institute. Along with a newly organized program for the chronic ventilator-dependent child, the Institute is providing specialized pediatric care not only for children in Delaware, but for youngsters across the nation. The cooperation of The Medical Center of Delaware and the Alfred I. duPont Institute is exemplified by joint ventures in expanded residency training, radiology, cardiac rehabilitation, subspecialty medicine, and the creation of a Ronald McDonald House for relatives, and provides a blueprint for pediatric care that is truly exciting. In addition, The Medical Center of Delaware and the Institute are working closely with a variety of state agencies in a number of important programs. Dr. Chronister provides added insight into one such program: state-wide services for the chronically handicapped child.

We hope that the readers of this issue will gain a greater appreciation for the ongoing developments in pediatrics in Delaware.

Michael L. Spear, M.D.

THE ROLE OF SUBSPECIALISTS IN A COMMUNITY PRACTICE SETTING

What is the appropriate role for pediatric subspecialists in a community practice setting in the 1980s? In addressing this question, first, I believe it is important to acknowledge that the acceptable standard of care for patients no longer has a community base, but rather a regional or national basis. It is no longer ethical, or indeed legal, for community pediatricians to offer a level of expertise for any particular clinical problem which is different from that which could be obtained from an appropriate subspecialist. To do so exposes the practitioner to a realistic and serious potential for legal liability. The fundamental question to address is how, on an individual case-by-case basis, does a practicing generalist pediatrician decide when the services of a subspecialist are required in order to provide optimal care for the patient? And when is such transition cost-ineffective, unnecessary, and disruptive to the patient and the family?

I am reminded of my own thought process as a pediatric resident and subsequent junior faculty member when I tried to keep all the complicated children with diabetes, asthma, seizure disorders, and cystic fibrosis in my general medical clinic under my sole care. Initially, this was easily done, since I had only recently learned the cutting edge management of these disorders from the subspecialists themselves. However, over time, I inevitably lost some of the certainty that I was able to provide the best care for all these groups of patients since I was unable to keep up with new developments in each subspecialty field. My decision to abandon another diagnosis from my list of those I was willing to manage independently was often occasioned by a clinical situation where it was glaringly apparent that my knowledge base was inadequate. This often led me to wonder what errors or omissions had been inadvertently committed on other patients. As my generalist practice grew, I gradually relinquished an increasing number of specialized diagnoses to sole management by subspecialists, keeping patients in which I was interested and able to remain current with the literature and trends of management.

Subsequently, through my training in pediatric rheumatology, I learned the subspecialist's

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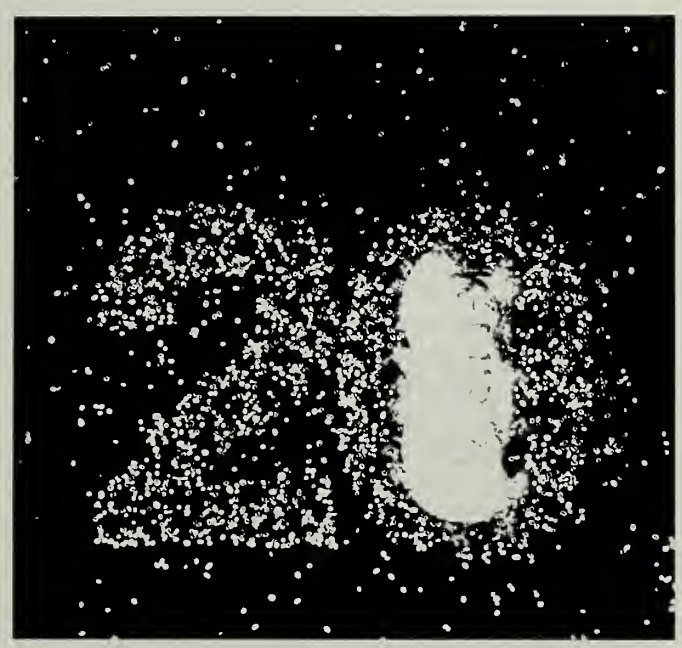
perspective of the immense value to patients of the subtle expertise in patient management which accrues to subspecialists through their having a volume of experience in a restricted field. This permits them to give precise and individually-sensitive prognostic information, to limit unnecessary invasive laboratory studies while obtaining critical necessary data, and to be certain that the patient is receiving optimal management. Yet, clearly not all asthma needs to be managed by allergists, and not all joint disease by orthopedists and rheumatologists, and not all patients with murmurs need to be seen by a pediatric cardiologist.

Ultimately, the practicing pediatrician serves as a gatekeeper and must be aware of practice limitations and know when a subspecialist has critical additional knowledge for management of a particular patient. At the same time the practitioner must not automatically "turf" all complicated problems to a subspecialist, thereby disrupting the generalist's important patient-physician relationship and restricting their practice profile to "otitis, gastroenteritis, and well child care." On the other hand, the subspecialist must be sensitive to not "stealing" the patient from the generalist. Optimal care results from effective teamwork between the practitioner, who has the most sensitive understanding of the patient and family needs, and the subspecialist, who has the critical medical information. Too often, the practitioner-subspecialist relationship is suboptimal due both to geographical and emotional separation of the community practitioner from the regional tertiary center, and because of mutual misunderstandings of each other's roles.

How should this interface between the pediatrician and subspecialist be managed? First, negative factors which inhibit an optimal relationship between generalist pediatricians and subspecialists should be minimized. There are four potentially negative factors. The first is financial issues--subspecialists may be viewed as having excessive fees and/or high incomes (without consideration given to the time required per encounter for management of complex problems). In the era of third party control of the cost of care, the additional expertise of a subspecialist may be viewed as too expensive or cost-ineffective for the benefit received by the patient. The second factor is the generalist's fear of being discredited by the subspecialist for prior management of the patient. The third factor is the potential loss of prestige by the generalist in the eyes of the patient's family for being unable to continue with management of the patient, i.e., "needing" to consult an expert and the generalist's fear of losing the patient (and perhaps others). And the fourth factor is potential jealousy



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3. The use of potassium salts in patients receiving diuretics for uncomplicated essential hypertension is often unnecessary when such patients have a normal dietary pattern. Serum potassium should be checked periodically, however, and if hypokalemia occurs, dietary supplementation with potassium-containing foods may be adequate to control milder cases. In more severe cases supplementation with potassium salts may be indicated

CONTRAINDICATIONS: Potassium supplements are contraindicated in patients with hyperkalemia since a further increase in serum potassium concentration in such patients can produce cardiac arrest. Hyperkalemia may complicate any of the following conditions: Chronic renal failure, systemic acidosis such as diabetic acidosis, acute dehydration, extensive tissue breakdown as in severe burns, adrenal insufficiency, or the administration of a potassium-sparing diuretic (e.g., spironolactone, triamterene).

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All solid dosage forms of potassium chloride supplements are contraindicated in any patient in whom there is cause for arrest or delay in tablet passage through the gastrointestinal tract. In these instances, potassium supplementation should be with a liquid preparation.

WARNINGS: Hyperkalemia—In patients with impaired mechanisms for excreting potassium, the administration of potassium salts can produce hyperkalemia and cardiac arrest. This occurs most commonly in patients given potassium by the intravenous route but may also occur in patients given potassium orally. Potentially fatal hyperkalemia can develop rapidly and be asymptomatic. The use of potassium salts in patients with chronic renal disease, or any other condition which impairs potassium excretion, requires particularly careful monitoring of the serum potassium concentration and appropriate dosage adjustment.

Interaction with Potassium Sparing Diuretics—Hypokalemia should not be treated by the concomitant administration of potassium salts and a potassium-sparing diuretic (e.g., spironolactone or triamterene) since the simultaneous administration of these agents can produce severe hyperkalemia.

Gastrointestinal Lesions—Potassium chloride tablets have produced stenotic and/or ulcerative lesions of the small bowel and deaths. These lesions are caused by a high localized concentration of potassium ion in the region of a rapidly dissolving tablet, which injures the bowel wall and thereby produces obstruction, hemorrhage or perforation.

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Metabolic Acidosis—Hypokalemia in patients with metabolic acidosis should be treated with an alkalinizing potassium salt such as potassium bicarbonate, potassium citrate, potassium acetate, or potassium gluconate.

PRECAUTIONS: The diagnosis of potassium depletion is ordinarily made by demonstrating hypokalemia in a patient with a clinical history suggesting some cause for potassium depletion. In interpreting the serum potassium level, the physician should bear in mind that acute alkalosis per se can produce hypokalemia in the absence of a deficit in total body potassium while acute acidosis per se can increase the serum potassium concentration into the normal range even in the presence of a reduced total body potassium. The treatment of potassium depletion, particularly in the presence of cardiac disease, renal disease, or acidosis requires careful attention to acid-base balance and appropriate monitoring of serum electrolytes, the electrocardiogram, and the clinical status of the patient.

Laboratory Tests: Regular serum potassium determinations are recommended. In addition, during the treatment of potassium depletion, careful attention should be paid to acid-base balance, other serum electrolyte levels, the electrocardiogram, and the clinical status of the patient, particularly in the presence of cardiac disease, renal disease, or acidosis.

Drug Interactions: Potassium-sparing diuretics, see **WARNINGS.**

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term carcinogenicity studies in animals have not been performed.

Pregnancy Category C: Animal reproduction studies have not been conducted with K-DUR. It is also not known whether K-DUR can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. K-DUR should be given to a pregnant woman only if clearly needed.

Nursing Mothers: The normal potassium ion content of human milk is about 13 mEq per liter. Since oral potassium becomes part of the body potassium pool, so long as body potassium is not excessive, the contribution of potassium chloride supplementation should have little or no effect on the level in human milk.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: One of the most severe adverse effects is hyperkalemia (see **CONTRAINDICATIONS, WARNINGS,** and **OVERDOSAGE**). There have also been reports of upper and lower gastrointestinal conditions including obstruction, bleeding, ulceration, and perforation (see **CONTRAINDICATIONS** and **WARNINGS**); other factors known to be associated with such conditions were present in many of these patients.

The most common adverse reactions to oral potassium salts are nausea, vomiting, abdominal discomfort, and diarrhea. These symptoms are due to irritation of the gastrointestinal tract and are best managed by taking the dose with meals or reducing the dose.

Skin rash has been reported rarely.

OVERDOSAGE: The administration of oral potassium salts to persons with normal excretory mechanisms for potassium rarely causes serious hyperkalemia. However, if excretory mechanisms are impaired or if potassium is administered too rapidly intravenously, potentially fatal hyperkalemia can result (see **CONTRAINDICATIONS** and **WARNINGS**). It is important to recognize that hyperkalemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration and characteristic electrocardiographic changes (peaking of T-waves, loss of P-waves, depression of S-T segment, and prolongation of the DT-interval). Late manifestations include muscle paralysis and cardiovascular collapse from cardiac arrest.

Treatment measures for hyperkalemia include the following:

1. Elimination of foods and medications containing potassium and of potassium-sparing diuretics
2. Intravenous administration of 300 to 500 ml/hr of 10% dextrose solution containing 10–20 units of insulin per 1,000 ml.
3. Correction of acidosis, if present, with intravenous sodium bicarbonate
4. Use of exchange resins, hemodialysis, or peritoneal dialysis

In treating hyperkalemia, it should be recalled that in patients who have been stabilized on digitalis, too rapid a lowering of the serum potassium concentration can produce digitalis toxicity.

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of the role of the other individual (the grass is greener...). Indeed, much of the difficulty in the relationship between generalists and subspecialists may stem from a basic misunderstanding of each other's respective role. Table 1 (page 189) attempts to capture the common misperceptions.

On the positive side, there are good reasons why a strong relationship between subspecialists and community generalists can be optimal for all concerned. In addition to improving the care of selected complex patients, the subspecialists can serve a major role in keeping the generalist up to date in management of common subspecialty problems through telephone contact as well as formal educational conferences. The subspecialist can also fulfill critical teaching responsibilities for residency programs, and conduct locally pertinent clinical research activities designed to improve available clinical care. Wilmington is fortunate to have a broad and increasing representation of local pediatric subspecialists. Their proper integration into the management of clinical problems in their area of expertise will result in gains for all concerned.

Robert A. Doughty, M.D., Ph.D.

Dr. Doughty is Physician-in-Chief of Alfred I. duPont Institute, and a consultant for the Department of Pediatrics, The Medical Center of Delaware.

PEDIATRIC INTENSIVE CARE

At a National Institutes of Health Consensus Conference held in 1983, Pediatric Intensive Care was defined as a multidisciplinary and multiprofessional medical/nursing discipline focusing on children who have sustained acute, life-threatening single or multi-organ system failure due to illness or injury. Central to this definition is the concept that such illnesses/injuries necessitates prolonged minute-to-minute observation and/or therapy in an environment capable of providing a high level of immediate intervention. This means that there must be geographically defined hospital beds dedicated to this activity, the Pediatric Intensive Care Unit (PICU). In addition, implied in this definition of intensive care is the role of a physician experienced and/or formally trained in pediatric intensive care who will take a leadership role in patient care, teaching, and administration of PICU. I believe that this definition holds today and for the foreseeable future.

The American Board of Pediatrics has recently defined appropriate training or experience for a pediatric intensivist:

1. Three years of fellowship in critical care after a pediatric residency; or

2. Board certification in pediatric cardiology, neonatology, pediatric pulmonology, or anesthesiology with appropriate critical care training, plus two years of critical care fellowship; or

3. Five years in the practice of comprehensive pediatric critical care (50% or greater).

The pediatric intensivist wears many hats, by providing both direct and consultative patient care, performing procedures such as endotracheal intubation, placement of Swan-Ganz catheters, etc., and teaching health professionals ranging from pediatric residents and fellows to emergency medical technicians, ambulance crews, and school nurses. The intensivist is often a triage officer, director of a transport team, quality assurance officer for intensive care, supervisor of the Code Blue Team, and administrator of a hospital-wide A.C.L.S./A.P.L.S. curriculum.

In community-based medical centers, the intensivist's role is somewhat different from that seen in a children's hospital or university hospital with a large, full time faculty. In the first place, the PICU in a community-based medical center is often run on the open staff model. In this model, the intensivist is more often a consultant to primary physicians who are delivering the care in the PICU. The PICU team is often comprised of practicing pediatric subspecialists and surgeons rather than full time staff. Training tends to be focused more on residents than on fellows, and research activities are not as prominently featured as they are in a university hospital.

One major issue faced by all hospitals with pediatric intensive care units in our current medical climate is monitoring the appropriateness of PICU admissions and length of stay. Several new scoring systems have been devised to evaluate the use of the PICU both in terms of actual severity of illness or injury and the intensity of monitoring and/or intervention. A recently published survey revealed that up to 25% of patients admitted to a PICU may not have ever required intensive monitoring and/or intervention, yet these patients used as much as 8% of total patient days in the PICU. Such patients, of course, have a low mortality rate, which may skew this indicator of the effectiveness and success of a PICU![1,2]

Pediatric intensive care is expensive. How is the full time salaried pediatric intensivist to be supported? In most institutions, income is largely derived from a combination of patient fees for direct and consultative care as well as the performance of procedures. Of particular importance in

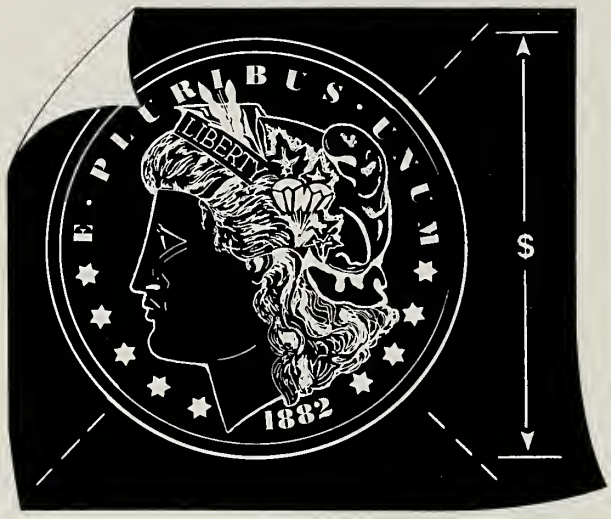
TABLE 1 -
BASIC MISUNDERSTANDINGS OF ROLE REALITIES

AREA	PRACTITIONER PERCEPTION		HOSPITAL - BASED SUBSPECIALIST PERCEPTION	
	OF HOSP. BASED SUBSP.	OF SELF	OF SELF	OF PRACTITIONER
INCOME	Too high	Too low	Too low	Too high
OFFICE OVERHEAD	Totolly subsidized	High costs ond rising	Hosp. Admin. unresponsive to needs	Have freedom to get whatever wont/need
PATIENT CHARGES	For to high	Inadequate reimbursement	Reimb. system complex ond unfair	Well reimb for simple repetitive tasks
INVASIVE PROCEDURES	Does too many	Not mony I can get reimb. for	Need information to provide best core	Orders lob. tests inoppropriotely
HOSPITAL & RESID. SUPPORT SERVICES	Has free use or residents to multiply obility to provide reimbursed core	Voriably useful High cost of teoching time vs. services obtoined in return	Teaching resid. is mojor time ond emotionol commitment Limited availobility of both.	Community attendings can just give their 6 hour per doy ond then leove
PROF. LIFESTYLE	Much free time for ocad. pursuits	Horried, hossled and underpoid	Works o 70-80 hr a week with little back-up for coll	Con't reoch practioners ofter 4. Assume they're home

REALITIES OF THE ROLES:
Incomes of both groups ore low overoll for physicions. Both groups often feel overcommitted, overworked ond underoppreciated.

Teoching con be both stimulating and o mojor droin of energy with little obvious reward.Everyone hos much to leorn (from eoch other) obout cost-effective ond oppropriote loboratory testing and core.

Upon closer inspection, green gross often is predominontly "crob gross".



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this regard is ventilatory mangement and invasive monitoring, which are increasingly covered by third party payers. In general, the presence of full time intensivists increases rather than decreases the census of the PICU and likewise increases the participation of other physicians because of the intensivist's commitment to and recognition of the value of multi-disciplinary care.

The Medical Center of Delaware has had a long tradition of pediatric intensive care fostered by the former Director of Pediatrics, the late Dr. Herman Rosenblum. Currently, the seven-bed acute and four-bed stepdown units are staffed by highly skilled nurses, a senior pediatric resident assigned to the PICU on a full time basis, and experienced pediatric specialists and specialty surgeons on the attending staff. There is also strong support from the clinical laboratories and the radiology department. The PICU at The Medical Center of Delaware admits between 400 and 500 patients a year. Approximately two-thirds of these patients have medical and one-third surgical diagnoses. In 1986, 100 children were admitted on the trauma service. With a patient acuity level comparable to that seen in PICUs located in children's hospitals and university-based hospitals, the 2.6% mortality rate at The Medical Center of Delaware in 1986 was comparable to that of these other institutions. We anticipate that the PICU will continue to be an important facility in our comprehensive pediatric care.

Michael E. Norman, M.D.

Dr. Norman is chairman of the Department of Pediatrics at The Medical Center of Delaware, and professor and associate chairman of the Department of Pediatrics at Jefferson Medical College, Philadelphia.

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HANDICAPPED CHILDREN: THERE IS PROGRESS!

Recent years have shown a dramatic increase in the provision of services for handicapped children, a development which will probably continue. A historical retrospect of Delaware's Services for Handicapped Children may help guide us through the many activities and services developed or in various stages of planning. It may even direct us toward new goals.

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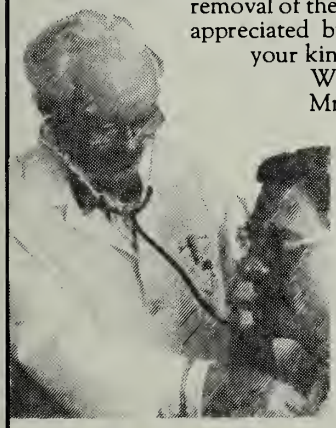

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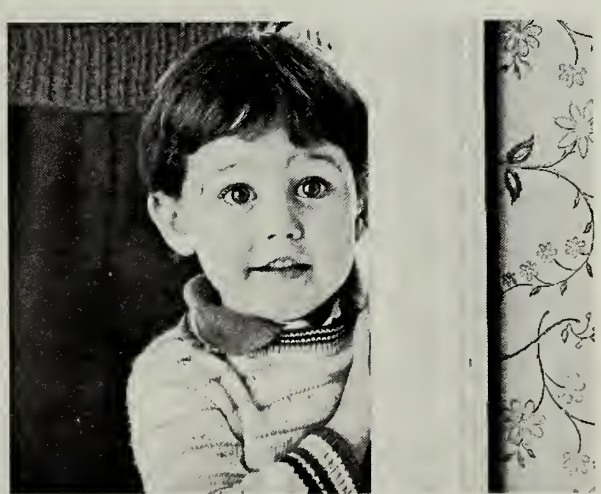
but significant section called Title V, pledging financial and technical support to the various states that created programs to improve the health and welfare of mothers and children. From this start came Maternal Child Health and Crippled Children's Programs and Services. The initial funding for Crippled Children's Services (CCS) was based on the states' number of people under 21 years, and on per capita income. Rural children were given twice the weight of children in urban areas. The appointment meant that federal dollars varied inversely with state per capita income. These stipulations resulted in Delaware receiving a minimum annual allotment. In effect, this resulted in Delaware having a conjoined effort of the Public Health, Maternal Child Health, and Crippled Children's Programs with the private sector. Otherwise, no programs or services of any significance would have been created in our state based solely on federal dollars. The Act has been amended many times in the ensuing years to reflect the changing needs of mothers and children and the ebb and flow of national interests in child health and welfare. Fortunately for Delaware, no amendment or change has altered the spirit of cooperation existing between private providers of medical care and the public sector on behalf of handicapped children and their families.

The initial thrust from the private sector began in the early 1940s with volunteer agencies such as the March of Dimes and when Alfred I. duPont Institute set out to become a nationally recognized center for the treatment of crippling conditions in children. Public Health and the Institute joined forces and as a result, Delaware became one of the first states to provide statewide services for crippled children. It soon became evident in jointly run clinics and in well child clinics conducted by Public Health that "crippling conditions" included a wide range of problems which interfered with a child's normal development. Like a magnet, these clinics began to draw and report on children who could not speak or hear, could not perform basic cognitive functions, and children with such problems as seizures, cleft lips and palates, and visual problems. These children, of course, had always been present, but they had remained isolated in their circumstances until more formal, regularly scheduled clinics offered a promise of help.

Through the 1940s and early 1950s, a number of basic support programs emerged. Crippled Children's Service dollars were used to establish the first Audiology Center at the Delaware Hospital. Subsequently, it became possible to establish the State Hearing Conservation Program. This



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was the first statewide program in the nation--a beautiful combination of private otologists, public schools, the hospital, and the Public Health Division. It initially served 169 children in 1953. This has grown to about 2,500 served in 1987. In the early 1950s, the Alfred I. duPont Institute, community orthodontists, and the Public Health-CCS planned and initiated the Cleft Palate/Oral Facial Clinic. This was later followed by the school-based Orthopedic Screening Program, a logical sequel to the Alfred I. duPont Institute's Orthopedic Clinic program.

More recently, CCS, now more appropriately called Handicapped Children Services, has called upon the private sector to assist in eliminating service inequities between New Castle County and the other less populated counties. Neurological services have been provided in Kent and Sussex Counties through various clinics since the 1960s, and there are now ongoing monthly clinics in both Kent and Sussex as well as services at the Stockley Center. State dollars were granted in 1985 to establish a pediatric ophthalmology clinic in Kent and Sussex Counties. This clinic, staffed by a Wilmington ophthalmologist, offers needed local services to infants and toddlers with visual problems. Likewise, a pediatric cardiac clinic providing evaluation and follow-up was also established in Milford at this time. None of these programs or services could survive without the commitment of private sector time and talents.

Over these same years, private agencies, such as the Delaware Curative Workshop, have continued to provide developmental and rehabilitative services to infants and children, but the situation has nearly exploded with resources recently. Through the Division of Mental Retardation, developmental nurses provide yearly intervention with the more severely involved young children both at home and at various sites. This system, in conjunction with Public Health nurses has shown increasing commitment to the developmentally disabled by providing evaluation, counseling, and treatment suggestions. Through the Public Health Services, a diagnostic team has started in Milford. Also, a service that reviews and serves as an advisory to families and includes various groups along with parents in coalition called "Arise" has been formed. The Easter Seal Society at their Georgetown site have been increasing their efforts with developmentally delayed and handicapped infants and children. A new and developing system entitled "Child Development Watch" is hoping to eventually provide a statewide service, consisting of the Public Health Services again working conjointly with various private services at The Medical Center of Delaware and eventually in Kent and Sussex Counties.

In conjunction with all these other resources, P.B. 99-457 has now resulted in some funding for the Department of Public Instruction to reach the lower ages down to three years of age for providing

services for the handicapped and their families. As this bill makes clear, there is an increased interest in incorporating families into the planning and management of the various resources.

With so many things on the horizon, we now have to consider where we are headed. It would seem at this time that it is even more critical for agencies such as the Coordinating Council for Handicapped Children to help with the coordination and coalition of these various resources. Underlying this is the great need for fiscal responsibility and a strong effort to avoid needless duplication of what can be very expensive services. Intertwined with this, we obviously have to continue to avoid any conflict of interest between various agencies.

Finally, there is no doubt that we must strive to incorporate families of children with handicapping situations into a collaborative effort. We need to encourage and facilitate parent-to-parent and professional-to-parent support and increase the availability of counseling for the families of these children. We need to support the development of adequate health care financing while establishing guidelines to control costs and make the services more efficient while at the same time bringing them closer to the families in need. This can only be accomplished by a concerted effort from all the participants of our society--professional, families, and governmental as well as the various private agencies.

Ted E. Chronister, M.D.

Dr. Chronister is a pediatric neurologist with a private practice in Wilmington, He is a senior member of the Department of Pediatrics and an associate member of the Department of Medicine at The Medical Center of Delaware. He is also an associate clinical professor in the Department of Neurology at Jefferson Medical College.

YOU'VE COME A LONG WAY, PEDIATRICS

In cleaning up my desk, I was going through some old papers and stuff and found one of those group photographs that the old Delaware Hospital used to take of all its interns and residents. I belong to the class of '64, and was one of three first-year pediatric residents. I remember one of us would be in charge of the ward patients and consultations from the Emergency Room, another would take the newborn nursery (not yet a plural), and the third one would take the private patients and be on "elective."

Now I ask myself: how could one single resident cover so much ground? But of course, our "major work-up" used to be a throat culture, occasionally a blood culture or a spinal tap and, when needed, to start an intravenous. Room 353, just because it was located across the hall from the nursing station, used to be our room-for-the-patient-to-watch-closely, and next to it, Room 354 housed all the respiratory-distressed children.

I also remember the Newborn Nursery being the largest room on the third floor, right across from the elevator. The room would always be overflowing with cribs of white and babies of all colors...including jaundice. Those were the days before yuppies, the Pill, birth control, rooming-in, and phototherapy. How could one single resident take care of full term and premature babies at the same time? (NICU was another abbreviation waiting to be invented.) But of course, we had five powerful tools on hand: isolette, oxygen, IV fluids, (occasionally clysis), exchange transfusion, and prayer. Prayer was very popular. Who would suspect that in 20 years progress would invent sophisticated phrases such as: rhogam, CPAP, pulse oximetry, transcutaneous oxygen monitoring, arterial blood pressure, central venous pressure, Swan-Ganz, cephalosporin, dopamine, nitroprusside, air transport, organ transplant, etc., etc.

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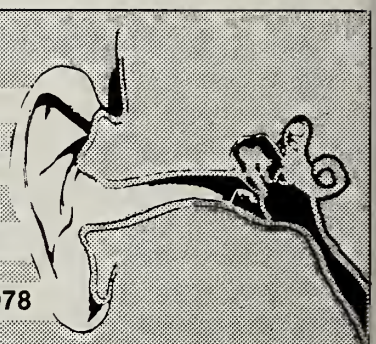

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And for radiology? Who would have dreamt that from a single x-ray would come such offsprings as: ultrasound, computerized tomography, and magnetic resonance imaging? Nowadays, it looks as though one cannot practice medicine without having read Isaac Asimov...

In the quest to help children better, the area in pediatrics that has experienced the most remarkable growth is, without doubt, outpatient services. Between The Medical Center of Delaware and the Alfred I. duPont Institute, what is being offered in outpatient clinics comes in all colors, shapes, and sizes; try one: pulmonology, cystic fibrosis, endocrinology, gastroenterology, developmental, genetics, speech and hearing, neurodevelopment, rehabilitation, spina bifida, sports medicine, neurofibromatosis, rheumatology, cleft palate, seizure, muscle, etc., etc.

But from all this progress what I know I miss not having had in the past is a Dyslexia Clinic. If we had one when I was growing up, I know for sure I would have been a better writer.

Memories...

Maurice Liebesman, M.D.

Dr. Liebesman is a pediatrician with a private practice in Wilmington. He is President of the Delaware Academy of Pediatricians.

PEDIATRIC NURSING: LESSENING THE EMOTIONAL TRAUMA

Today, pediatric nurses practice in a variety of health care settings. They are challenged with diagnosing and treating patient responses to potential or actual health problems through holistic assessment, patient education, and supportive and rehabilitative care to aid the patient in achieving an optimal state of health.

Children are extremely vulnerable and fearful when it comes to health care. Therefore, pediatric nurses base their practice on developmental needs and the nursing diagnoses of fear, knowledge deficit, and diversional activity deficit to help minimize the stress of treatment or hospitalization.

Pediatric nurses believe that the child is a unique individual who is part of a family unit, and so encourage parents to participate in their child's care as much as possible. Since the child is separated from daily routines and peer groups, the Pediatric Department at The Medical Center of Delaware has both a Child-Life and School program to help normalize the hospital experience and provide diversional activities.

The playroom is considered a safe place for children where they can participate in diversional and therapeutic play. Many studies have shown

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that since play is the primary means by which young children learn, it is the best way to prepare them for hospitalization and treatments. Play enables children to learn through manipulation and allows them to express the fears and concerns which they often cannot verbalize.

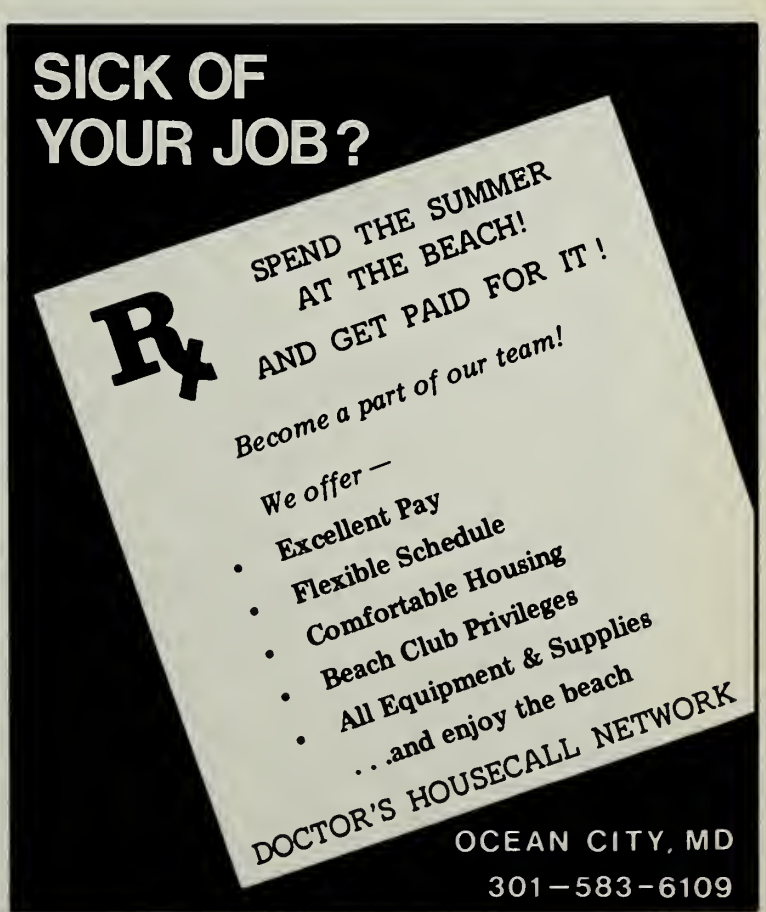
Child-Life therapists insure that no treatments are done in the playroom. However, nurses and doctors are welcome to "play" with the children and assess their physical and developmental status in a non-threatening environment. Also, during the holidays, special programs are planned with the support of volunteer and community groups.

The Young Adult Unit has a game room which provides a place for adolescents to socialize, play pool, and listen to music. Weekly movies and ice cream festivals make the hospitalization a bit more tolerable for this age group.

Realizing that school is a normal activity for children and adolescents, the Brandywine School District provides the hospital with a teacher. The hospitalized patients are encouraged to attend school and keep up with their academic work. Children who are hospitalized for a period of time benefit greatly by this program since they receive credit for attending the hospital school.

Preparation for treatments and hospitalizations is primary to the nurses' care to relieve fear and promote understanding. If children are not prepared, their fantasies are often scarier than what actually will happen. One way to help familiarize the child with health care and hospitalization in a non-threatening way is through hospital awareness programs. These programs can be formal presentations for a school class or part of a health fair. Taking a school trip to the hospital or having a pediatric nurse go to the school allows the child to become acquainted with hospital routines and treatments without the anxiety of a pending hospitalization. For planned surgical procedures, the young child and family are invited to a weekly pre-admission program, "Preparing Your Child for Surgery." During this hour program the family is oriented to hospital routines and receives a tour of the Pediatric Unit and the Operating Room.

Every interaction the nurse has with the patient and family is an opportunity for health teaching. However, shorter hospital stays and the emphasis on home care has created the need for formalized teaching programs to prepare the patient and parents to continue specialized care at home for their child with such devices as a central venous



access device or a home apnea monitor.

Parents of infants who are discharged on home monitors display a variety of concerns. Some parents are grateful for equipment they can have in their home to alert them of any potential problems. However, others are petrified that their child will need complete resuscitation each time the monitor alarms. Home monitoring often creates child care and financial restraints on the family. The infant home monitoring coordinator assists the parents in having a healthy monitoring experience. She has monthly support group meeting, follow-up telephone calls, quarterly newsletters written, along with the Public Health Nurse referral for home visits. The coordinator supports the family through all phases of monitoring their infant.

Central venous access devices are becoming popular in the pediatric population for children needing long term laboratory work, chemotherapy, intravenous antibiotics, and hyperalimentation. Gilbert Getwell, a patient puppet, joined our nursing staff over a year ago to assist nurses in teaching children and parents complicated procedures, especially dresssing changes, administering medications, heparinization, and emergency care of these devices. Gilbert allows the child to perform the skills on him while parents learn to care for their child's device. The role reversal helps the child cope with the situation. Often the children will discuss their fears and concerns with Gilbert before verbalizing them to parents or staff.

Working with children and their families is both challenging and rewarding. Seeing a child give his own insulin injection for the first time, or parents maintaining sterile technique while doing a dressing change and heparinizing a central venous device, continues to make nursing a worthwhile and rewarding profession.

Jacqueline W. Levett, R.N., M.S.N.

Ms. Levett is a pediatric clinical specialist at The Medical Center of Delaware.

CHEERS FOR DR. SPEAR

Dr. Michael Spear has done an admirable job in assembling this interesting array of papers on various aspects of pediatrics.

Delaware has a long tradition of caring about and for children: Drs. Margaret Handy, Marjorie McKusick, Margaret O'Brien, Herman Rosenblum, Charles E. Wagner, Alfred Shands, and R.O.Y. Warren, to name just a few, would be proud and happy to see the present state of the art.

We thank Dr. Spear and his colleagues.

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DELEGATE'S REPORT: 1987 INTERIM MEETING OF THE AMA HOUSE OF DELEGATES

The Interim Meeting of the AMA House of Delegates was held in Atlanta, Georgia, from December 6 through December 9, 1987. The Medical Society of Delaware was represented by its President, Martin J. Cosgrove, M.D.; Delegate Daniel A. Alvarez, M.D.; Alternate Delegates Alfonso P. Ciarlo, M.D.; and Robert E. Heckman, M.D.; as well as the Executive Director, Anne Shane Bader. Dr. Cosgrove appointed Dr. Ciarlo to serve as Delegate for the Meeting.

The AMA House of Delegates was composed of 411 seated Delegates, including 327 representing state associations, 74 representing national specialty societies, and ten representing students, medical schools, residents, hospital medical staffs, military physicians, the USPHS, and the VA. Of the specialty society seats, five were newly admitted at this meeting. They were the American Rheumatism Association, the American Association of Electromyography and Electrodiagnosis, the American Society for Dermatologic Surgery, Inc., the American Society of Clinical Oncology, and the American Society of Maxillofacial Surgeons.

The delegation of the 1987 Interim Meeting considered some 76 reports and 145 resolutions. It is not the intent of this report to detail every item of business, but to summarize the major issues considered as well as to mention any business which may be of particular interest to the Medical Society of Delaware.

The continuing professional liability crisis topped the legislative agenda at the Interim Meeting. The House adopted a comprehensive report prepared by the AMA's Special Task Force on Professional Liability and Insurance and the AMA's Advisory Panel on Professional Liability. The report describes recent federal activity and recent alternatives to the civil justice system. It also discusses risk retention groups, procedural based insurance rating plans, and the availability of liability insurance for Directors and Officers. In a resolution, the House supported and commended Florida State Medical Association for its work toward having an alternative mechanism for resolving liability disputes enacted. Termed "MICA," it appears to have some similarity to the mechanism used for Workmans' Compensation. The House also passed a resolution asking the AMA to support state associations' efforts to procure the enactment of legislation that will limit lawyers' contingent fees.

The AIDS epidemic continued to be the focus of much of the attention of AMA delegates. Ethical issues that have been raised by the AIDS problem were a priority. The Reference Committees dealing with the AIDS issue heard profuse testimony regarding the physician's moral and ethical responsibilities to AIDS victims. The House filed a report of the Ethical and Judicial Affairs Council which provides guidelines on three significant points. First, a physician may not ethically refuse treatment to a patient because he is seropositive. Second, infected patients should be persuaded by the physician to cease activity which would put a third party at risk of infection. If the patient is not persuaded, the physician should notify the public health authorities. If the authorities fail to act, the physician should then notify the third party who may be endangered. Third, any physician who knows he has AIDS should not participate in any activity that may expose others to risk.

The House also adopted a report that describes AMA activities related to the continuing education of both health care professionals and the general public with regard to the control of AIDS. These activities include the distribution of educational material, local seminars and conferences, and media announcements. A second report, from the AMA Council on Scientific Affairs, outlines recommendations that the AMA work diligently to encourage the government to increase its funding

and efforts in educating the public, preventing spread of the disease, and in research to find a solution to the growing problem.

There was a lengthy debate before a resolution asking the AMA to change its position regarding mandatory HIV testing of prisoners was referred back to the Board. From observations at Reference Committee meetings and informal discussions among delegates, the issue of mandatory testing for various groups is still controversial, and far from being permanently resolved.

Another area of concern in the delivery of health care that received House attention was the growing shortage of nursing personnel in the United States. The House adopted a report from the Board of Trustees that calls for a continuation of all levels of nursing education, including those that were previously scheduled to be phased out. The report also directs the AMA to be supportive and cooperative with government and private agencies who are involved in the recruitment and education of nurses as well as to those agencies who are involved in providing continuing education for nurses. The House also supported the Board's suggestion that the AMA should do everything it can to support professional and economic incentives that will keep nurses on the job.

Recent attention given to working conditions for resident physicians resulted in a study and report from the AMA's Council on Medical Education outlining new guidelines that accrediting agencies could use to reduce overwork by residency programs. The Council asked the House to recognize existing problems with supervision of residents providing patient care, to urge the ACGME to revise their guidelines to emphasize the importance of supervision, work hours, and stress, and to urge each residency review committee to define supervision and maximum work hours. Although the AMA's guidelines encountered stiff opposition from some physicians during the Reference Committee meeting, they easily passed in the House.

Once again, Medicare reimbursement was a topic that demanded strict attention from the delegates at the Interim Meeting. It was the issue that created the most vociferous reaction from the greatest number of delegates. Delegates considered a comprehensive informational report providing an update on the current status of physician reimbursement. The greatest number of resolutions introduced to the House dealt with the many aspects of Medicare reimbursement. The House approved a resolution that calls on the AMA to educate the public that third party schedules are benefits to the insured but do not obligate physicians to accept their payments in full unless a contract of agreement has been entered into by the physician and the third party.

The House of Delegates also adopted a resolution that would require the AMA to actively oppose, by any appropriate legal or political means, any action by any body that would require mandatory acceptance of assignment of Medicare benefits. However, the same House also adopted a resolution asking the AMA to assist state societies in developing voluntary Medicare assignment programs for the elderly with limited means.

The number of resolutions introduced that addressed the inequities in Medicare's MAAC program seemed to be endless. Among the policies approved by the House regarding MAACs were those to seek legislation to eliminate the unfair fee distortions created by MAAC implementation and to exert every effort to prevent physicians from being penalized or prosecuted for possible MAAC violations. Resolutions were passed to work for repeal of categorization of physicians as "participating and non-participating," for repeal of the provision requiring notification of patients receiving elective surgery in which the patient would be expected to pay the balance when a charge is more than $500, and for repeal of the provision to require physicians to refund payments associated with services that Medicare deems to be medically unnecessary.

A resolution which seemed to summarize the intent of the House called on the AMA to communicate to the government that increases in Medicare reimbursement need to be universal, that current reimbursement needs to be adjusted, and that discrimination between so-called participating and non-participating physicians needs to be ended.

The discussion of PROs was highlighted by the report that significant progress has been made by the AMA in working with HCFA as well as Congress in listening to the concerns of physicians and attempting to make the PRO program equitable. Resolutions reinforced previous concerns, urged that government-managed hospitals be included in the PRO program, and that the AMA work to eliminate bounty systems used to reward employees based on the number of sanctions imposed and penalties recovered.

The Board of Trustees submitted a status report of the Harvard/AMA Relative Value Study. A resolution passed by the House asked the Board to seek the input of all specialty organizations. The resolution also asked the Board to develop specific methodology for implementation of the RVS and a time frame to achieve full realignment.

Regarding organizational matters, the AMA announced new record membership. The incentive

program which includes financial incentives to societies who increase AMA membership was explained. Included in this program is the method whereby Delaware, as a new unified state, will receive financial incentives to remain unified which are proportional to AMA revenues paid.

The Board also presented a recommendation that was approved by the House of Delegates to form an in-house, for profit insurance agency to handle the AMA's insurance plans for members and non-members. This would increase the AMA's income and may result in even better service to its members.

Methods to encourage participation of both residents and foreign medical graduates in organized medicine at all levels was discussed.

In other business, the House of Delegates voted to have the AMA work with the Joint Commission to assure equitable participation of physicians during on-site surveys. The House called for an AMA study on the implications of hospitals' contractual relationships with alternative health plans. Also, a resolution was adopted calling for the development of guidelines for the role of medical director that will result in good working relationships between the staff and the director, and which will maintain the staff's autonomy.

During the address of the president, William S. Hotchkiss, M.D., two major challenges facing the profession were covered. He stressed the importance of maintaining unity in medicine, and commended the AMA for its efforts to foster good working relations with the specialty societies. Dr. Hotchkiss also emphasized the need for physicians to maintain control over patient care. He indicated that the profession could only succeed by having all physicians stand together and to become personally involved.

The delegation from Delaware to the Interim Meeting of the AMA was proud to represent the members of the Medical Society of Delaware. It is suggested that members refer to the December 18, 1987 edition of the *American Medical News* for more detailed discussion of the Meeting proceedings. However, the delegates are always willing to answer any questions and to convey any concerns of Delaware physicians to the next AMA meeting. Moreover, it should be repeated that any AMA member is welcome at the AMA Annual and Interim Meetings, and Reference Committees will hear the opinions of any member. The official Delaware delegation would be pleased to have any member of the Medical Society of Delaware join them at the next meeting in Chicago June 26-30, 1988.

Daniel A. Alvarez, M.D.
Delegate to the AMA

Deaths

MARTIN B. PENNINGTON. M.D.

Dr. Martin Beadenkopf Pennington, a general practitioner for 50 years, died December 11, 1987 of heart failure. He was 79.

Dr. Pennington attended University of Alabama, and graduated from Hahnemann Medical College in 1935. He began his medical career in Newark in 1936, after completing his internship at the Memorial Hospital. In 1937, Dr. Pennington opened an office in Wilmington, and practiced there until his retirement in 1980. During his career, Dr. Pennington was appointed medical consultant to the rehabilitation division of the State Board of Vocational Education in 1945, a position he held until 1977. He was a captain in the Army Medical Corps, serving with the 13th Infantry, 8th Division during World War II.

Dr. Pennington was a past president of the Delaware Chapter of the American Academy of General Practice. He was a fellow of the American Academy of Family Physicians, a member of the American Medical Association, the Medical Society of Delaware, and the New Castle County Medical Society.

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In Brief

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CLINICAL MEETINGS AND NOTICES

AIDS CONFERENCE

Mark your calendars for an all-day Conference on AIDS, to be held Saturday, April 16, 1988, at Clayton Hall, University of Delaware. The sponsors are the Medical Society of Delaware, the Delaware State Dental Society, and the Delaware State Bar Association. National speakers have been contacted to speak on AIDS-related problems concerning all professionals today. The morning session will address the special interests of the dental and medical professionals, and the afternoon will be devoted to legal issues surrounding the AIDS patient. More information will be forthcoming.

CLINICAL TRAINING PROGRAM IN FLEXIBLE SIGMOIDOSCOPY

The Philadelphia Division of the American Cancer Society will present a program, "Clinical Training Program in Flexible Sigmoidoscopy for Primary Care Physicians," on April 30, 1988, at the Albert Einstein Medical Center. The program consists of three parts: a didactic presentation, hands-on experience with anatomic models, and supervised clinical experience to be scheduled on an individual basis. For more information, contact Shirley Starkman at the Philadelphia Division, American Cancer Society, 1422 Chestnut Street, Philadelphia, Pennsylvania, 19102, or call 215-665-2920.

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The 25th Annual Infectious Disease Symposium will be held May 2-6, 1988, at the Delaware Academy of Medicine Building. For more information, contact Dr. William J. Holloway, Infectious Disease Research. The Medical Center of Delaware, PO Box 1668, Wilmington, Delaware, 19899, or call 302-428-2744.

COMPUTER APPLICATIONS IN RADIOLOGY

Hilton Head Island will be the site of the Ninth Conference on Computer Applications in Radiology on June 1-4, 1988. This course has been accredited for up to 21 hours in Category I of the AMA. For more information, contact Janice Ford, Continuing Education Coordinator, Department of Radiology, Hospital of the University of Pennsylvania, 3400 Spruce Street, Philadelphia, Pennsylvania, 19104 or call 215-662-6904.

MARYLAND MEETING

The Maryland Academy of Family Physicians will hold their 40th Annual Meeting and Scientific Session May 11-15, 1988 at the New Sheraton Fountainbleu Inn and Spa in Ocean City, Maryland. The program is approved for up to 32.75 hours of AAFP prescribed credit. For brochure and registration information, contact the Maryland Academy of Family Physicians, 5700 Executive Drive, Suite 110, Baltimore, Maryland 21228, or call 301-747-1980.

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President's Page

THE PITFALLS OF PEER REVIEW

In an earlier President's Page, I touched briefly on the current dilemma of peer review in our profession.

As members of a profession, we are responsible for the proper monitoring and review of our colleagues. Many of us perform this duty regularly: at the state and county level, in our institutions, and in our hospital departments.

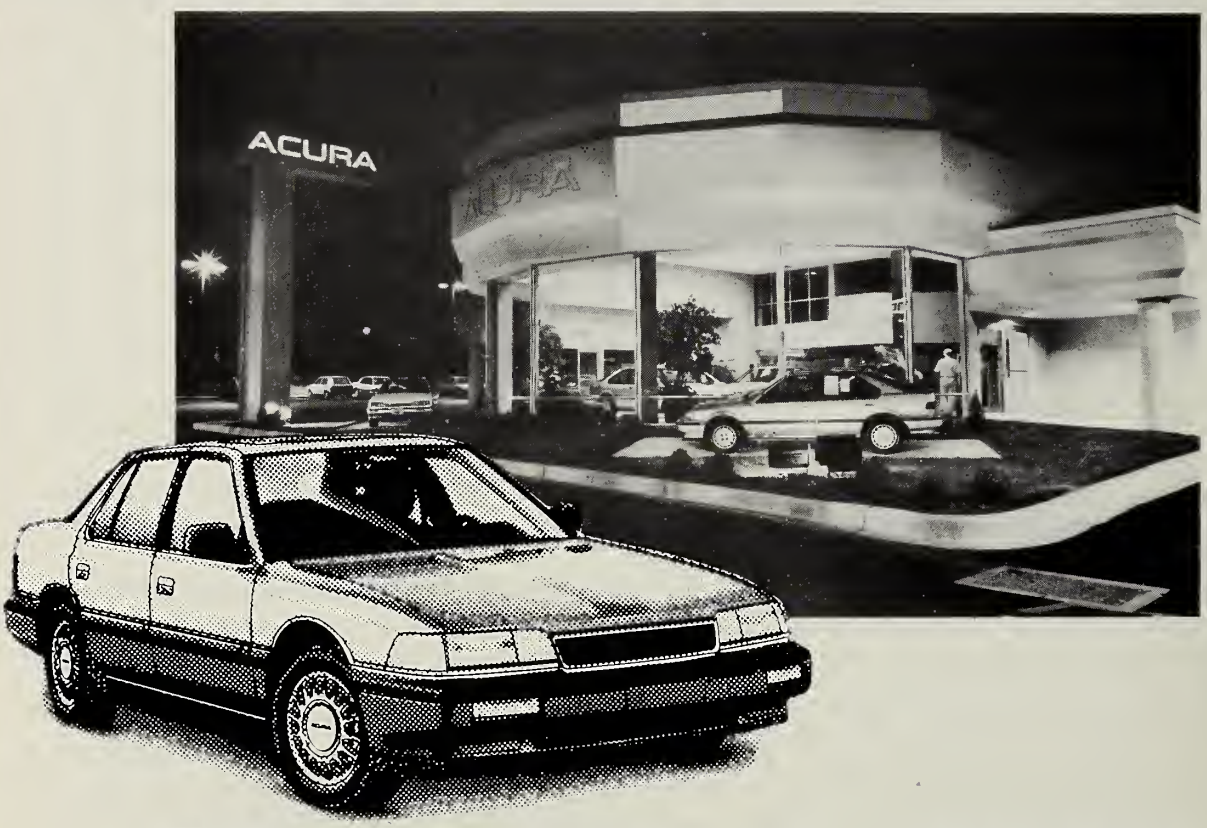
Physicians participating in the peer review process, however, are increasingly in possible legal jeopardy for libel and slander, and by antitrust litigation for restraint of trade and competition. Inadequate or cursory peer review may also place the reviewer at malpractice risk.

Mr. Victor F. Battaglia, the distinguished attorney for the Medical Society of Delaware, addressed the issue of the peer review dilemma at the House of Delegates Meeting last November. He presented an overview and examination of the problem and a possible solution. I believe his thought provoking and incisive remarks deserved publication *in toto* for the education and consideration of all members of our society.

I urge all to consider Mr. Battaglia's remarks which appear elsewhere in this issue of the *Delaware Medical Journal.*

Martin J. Cosgrove, M.D.

drive one before bedtime and call us in the morning.



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THE DILEMMA OF THE NURSING SHORTAGE

John M. Levinson, M.D.

Introduction

My discussion of the nursing shortage dilemma first considers the nursing shortage on a national basis, then as it specifically relates to the state of Delaware, then presents the recommendations of the Governor's Task Force, and finally a set of recommendations of my own.

On the National Level

The U.S. Department of Health and Human Services reports that the output of nurses has doubled over the past 30 years, a rate greatly exceeding population growth; licensed registered nurses now number 2.1 million. From 1977 to 1984 the number of employed nurses increased by 55% compared to only an 8% growth in population. Registered nurses are the largest single group of health professionals in the medical care delivery system.

Between 1980 and 1986, 414 hospitals in the United States closed, accounting for 56,628 beds. Of the 1.5 million RNs employed, 68% work in hospitals. In spite of this, we have a rapidly increasing shortage of these key personnel. The American Hospital Association in 1986, reported that high vacancy rates for nurses were disrupting hospital care. In 1972, hospitals employed 50 nurses per 100 patients, but by 1986 the figure had increased to 91 nurses per 100 patients, an 82% expansion. It must be realized that with shorter hospital stays the average hospital patient is sicker, and more highly skilled personnel are necessary. Aides and licensed practical nurses have frequently been replaced by registered nurses. In 1968 RNs accounted for only 33% of the hospitals' total nursing personnel, by 1986 registered nurses accounted for 58%. The growing deficit of nurses is real. With a more sophisticated medical establishment, an aging population, ever increasing demands upon the health system, and the frequent use of RNs rather than lesser-skilled personnel, the shortage will increase.

Unpublished National League for Nursing data disclose that since 1983, enrollments in nursing schools have dropped by 20%. The number of new nurses graduating annually is predicted to fall another 20% by 1995, and a decline is noted nationally in enrollments in all types of nursing programs.

Where are the nursing students going? They are not leaving the health field, but the National American Council on Education reports they are choosing a different goal. A 1968 survey revealed that the number of

Dr. Levinson is a member of the Health Care Financing Task Force and Delivery Alternatives of the State of Delaware Department of Health and Social Services. This paper was adapted from an address given in October, 1987, to The Nursing Shortage Seminar, conducted by Inservice Training Institute.

freshman women interested in nursing was more than three times the number of women who said they planned to study medicine. In 1986, the number of women intending to be physicians surpassed the number intending to be nurses by a ratio of five to four. There are also fewer high school graduates than a decade ago, which further complicates the situation.

Why is the nursing profession, of whom 97% are women, failing to attract students? My own observations confirm what is in the nursing literature. The number one reason is money. According to the *National Journal of Nursing*, starting salaries for hospital staff nurses in 1986 ranged from a low of $14,722 (at a Dallas area hospital) to a high of $32,885 (at a San Francisco hospital). Salaries for experienced staff nurses ranged from less than $20,000 to more than $35,000, with top rates of $48,000 reported by hospitals in Boston and Chicago. Smaller hospitals appear to pay less, and although at long last nursing salaries at entry-level positions following nursing training are at par with those of other similar professionals, there are few financial incentives for an experienced staff nurse as the years go by. These lack of incentives are noted by young women as they choose a professional career, and also make it tempting for skilled nurses to leave the hospital environment.

The past several decades have seen unprecedented opportunities for women in the fields of business, engineering, and all professional careers. Among the attractive facets to these new careers are lack of night and weekend hours, and the duty rosters still integral to nursing.

One of the compelling reasons not to choose a nursing career, or to look for employment outside the hospital environment, is lack of job satisfaction. Too frequently, nurses are shifted to tasks for which they are ill-suited or untrained, placed in adminstrative posts for which they are not prepared and where their nursing skills are wasted. Lack of appreciation by physicians is another important factor. I have personally noted on numerous occasions how appreciative a staff nurse has been when I consulted her and asked for her suggestions on patient management. Nurses are far more skilled than ever before; they wish to participate in clinical decisions. An improved relationship with physicians would go a long way to improve the job satisfaction of nurses.

Medicare's prospective payment system, the increasing need for nursing personnel in nursing homes and outpatient facilities have also caused further drains on the pool of available personnel.

The constraints of time preclude me from offering further documentation on a national level. I would, however, refer you to the September 3, 1987 issue of *The New England Journal of Medicine*. The Health Policy Report, entitled, "Problems Facing the Nursing Profession," and the Special Report, entitled, "The Nurse Shortage: Myth or Reality," provide an indepth understanding of this serious situation that impacts us all.

On the Local Level

Having touched upon the national scene, let us now review what is happening in Delaware. Little hard data is available, but I have been impressed by the interest and knowledge shared with me by the directors of nursing at the state's various schools of nursing and the hospitals, as well as the ideas put forth by many hospital nurses with whom I have informally discussed the subject. Surveys are in progress, but not yet available to give us information we need locally to fully understand the problems of the nursing shortage in our state.

There are approximately 7500 licensed RNs in Delaware, of whom about 6000 are actively employed in full or part-time positions. The president of the Association of Delaware Hospitals, Inc., led me to believe that there are approximately 500 nursing positions available. According to the American Hospital Association, vacancy rates in hospital staff nursing jobs more than doubled to 13.3% from late 1985 to late 1986; Delaware may be slightly better off than some other states.

What training for registered nurses is available now in Delaware? Beebe Hospital in Lewes conducts the last of the three-year diploma schools of nursing in the state. Beebe used to graduate up to 18 RNs per year; 12 graduated in 1987 and ten are anticipated to graduate in 1988. The age of the students is increasing, which means these nurses have shorter careers. Applicants are not deterred by tuition problems, but recruitment is deterred by a lack of appreciation of the job of being a nurse, and of course, by financial incentives. If federal funding for the school is withdrawn, there is a question whether the school will continue.

Delaware Technical Community College, which offers an Associate Degree in Nursing, averages about 30 graduates yearly in its program which takes approximately three years. The program is frequently filled with older students, and it is not uncommon to see students leave because of problems with babysitting and finances. Another, two year program offered since 1973 at the Stanton campus graduates 60-70 RNs. At the Dover campus of Delaware Technical Community College, a one year licensed practical nurse course graduates approximately 25 to 30 students yearly.

For some years almost 200 students received a BS in Nursing annually from the University of Delaware. In June, 1987, only 165 received this degree, and the projection for the next three years shows a gradual decline until at best 100 students will graduate in 1990. All of the problems we have seen on a national level impact on the enrollment at the University of Delaware. Additionally, due to increased tuition costs, nursing scholarships are now needed. A steering committee has been formed with the directors of nursing from St. Francis Hospital and The Medical Center of Delaware to analyze their problems of supply and demand and to look for ways of educating and retaining more nurses.

Wesley College in Dover, a private institution, has offered an Associate Degree in Nursing to 40-50 students per year for more than 20 years. Since 1982 they have offered a four year degree program to six to ten students annually. Their enrollment is not full; Wesley officials told me one of the biggest needs for increasing enrollment is a better image of the nursing profession. Shift work in nursing was also pointed out as a detriment to recruitment, as well as all of the other options available for career paths.

Wilmington College has a program newly initiated in

1985. All the students are part-time working RNs who have either a diploma or Associate Degree and who can in two additional years receive a Bachelor of Science in Nursing. The College anticipated graduating seven nurses in December, 1987, and 30 in 1988. The students' motivation for this continued education appears to be a chance to obtain a wider range of positions in the nursing field, as well as larger financial gain.

Those of us who have been around for a few decades remember when there was a Delaware Hospital School of Nursing, Memorial Hospital School of Nursing, St. Francis Hospital School of Nursing, and Wilmington General Hospital School of Nursing. The Milford Hospital School of Nursing closed in 1976. However, their Board of Directors instituted an innovative program for nursing scholarships available to students who promise to work at the hospital a year for every year they have been given the scholarship. Similar programs though few in number, have been tried elsewhere and have done well. As at other hospitals in our state and nationally, Milford offers 100% tuition reimbursements to full-time nurses who take courses leading to advanced degrees in nursing on their off-time. An active recruitment program is in place at Milford which has already brought in nurses from as far away as Canada.

The Medical Center of Delaware (MCD) employs 2000 nurses in all categories. Their yearly attrition rate is 10-12%, considered low compared to most institutions. There are shortages in critical areas, such as intensive care and intensive cardiac care, and in February 1987, MCD instituted an internship program in critical care areas to train on-site personnel. More nurses with these specialized skills are needed nationally, and specialty recognition in these areas is most desirable.

The directors and staff at MCD recognize all of the problems already enumerated as to why people do not choose nursing careers, stressing career opportunities without a 24-hour day, job satisfaction, and financial incentives for senior staff. They also recognize a need to increase productivity of the RN, and to use nurse extenders, ie, lesser-trained personnel for tasks that do not require the skills of the RN.

At The St. Francis Hospital, a nursing recruitment and retention task force has applied an aggressive and innovative approach to the problem. There, 470 nurses were asked as professionals what they felt would make their jobs more attractive. Increased salaries with an increased differential for the less-desirable night and weekend shifts led the list. More responsibility for the LPNs, along with faculty appointments in area colleges and universities to further their knowledge and involvement in nursing were also noted. The Task Force is not offering Caribbean cruises, nor finder's fees for locating nurses, and although they could use 40 more nurses, they have not resorted to agencies. Instead, premium salaries are being paid for the night shift. RNs who work only on night shifts will now be paid $43,000 per year, and LPNs $31,000 per year.

Escalation of nursing salaries in one local hosptial will undoubtedly cause salary escalations in others, and eventually such changes will sweep the country. This will further impact on health-care costs, which rose from 6% of the Gross National Product in 1965 to nearly 11% in 1985. But as well-paid professionals in the medical field, we physicians must appreciate that these changes are necessary, and it may possibly require closer to 13% of the GNP to provide the type of health care this nation wants.

At the final meeting of the Governor's Health Care Cost Management Commission on June 15, 1987, in addition to the 14 recommendations of the Health Care Financing Task Force, Secretary Eichler presented three which deal with the current nursing shortage in Delaware and the potential for shortages in other health-related professions.

1. The Health Resources Management Council should identify health-care personnel needs, particularly nurses, as a health-care priority by monitoring vacancies with attention to specific kinds of care, predicting future needs, and recommending further public policy and action to assure training, recruitment, and retention of needed care-givers.
2. Development of a personnel pool of nursing should be recognized as a priority for the State's economic development and health-care needs by reviewing existing nursing education programs using existing training programs to maximize opportunities for entry-level careers in health care, determining appropriate incentives to encourage entry into health care fields where there is a shortage of personnel (comparable to recent efforts to increase the pool of teachers), and using State funds to establish scholarships and loan programs with forgiveness of payback if recipient serves in a Delaware health-care institution.
3. The DIMER Board should make recommendations for using its existing authority to further the development of nursing and other health-related professions for which shortages exist. (Pending H.B. 252, with Commissioner Soles as primary sponsor, establishes scholarships and loans for Delaware students to enroll in nursing training programs to become registered nurses and pursue careers in Delaware hospitals and clinics.)

These recommendations were unanimously and enthusiastically received by the Commission. Secretary Eichler is deeply concerned about all these issues, but as a pragmatist, I question how far these recommendations will go through the bureaucracy necessary to implement them.

Recommendations

My own recommendations for solving the dilemma of the nursing shortage fall into categories which I shall designate the "Six Rs."

1. *Recruitment.* The nursing profession must aggressively recruit at the high school and college level, as well as among older women who have completed their families or who are single parents. Scholarships with innovative. payback arrangements such as obligations to work in local hospitals, as has been done in Milford, should be tried. Foreign students and foreign nurses should also be recruited, realizing that there are often cultural problems with such personnel, and that this may only be a temporary expedient.

2. *Retraining.* LPNs and RNs not currently in the labor force should be encouraged, and if necessary, subsidized to take the refresher courses approved by the Board of Nursing. There is reason to believe that a number of retired nurses, if given the courses tuition-free, might return to career positions. Tuition reimbursement of 100% for upgrading the knowledge and certification of existing nurses employed full time by hospitals should be more widespread.
3. *Retention.* The efforts at St. Francis Hospital are exemplary and speak for themselves. An exit interview for all nurses leaving a hospital might give insight into specific institutional problems.
4. *Recognition.* Nurses are professionals who must be treated as such. They must be given responsibilities commensurate with their training, ability, and experience. They must be able to participate more at all levels of decision-making in health care. Physicians and hospital administrators must be sensitive to their fundamental need for increased job satisfaction.
5. *Reimbursement.* Current entry-level salaries at all institutions should be re-examined now and on a yearly basis. Flexible hours and more usage of part-time personnel are critical. There should be an increased salary level for nurses who have special training and certification in critical areas. Retirement plans and employee benefits must be competitive with industry.
6. *Restructure.* Nurses must be used efficiently to draw upon their knowledge and experience. They should be more involved in patient care, not only in their areas of expertise, but in a caring way. Nurse extenders are needed to serve in secretarial positions, as nurses' aides, and in some more sophisticated areas that do not require the knowledge of the RN. A combination of all these suggestions would lead to higher productivity.

Conclusion

The AMA has not always been as sensitive as it might to changes requested by the ANA. However, I see no reason why the Delaware Nurses Association should not approach the Medical Society of Delaware and ask for its assistance in addressing the problems discussed here. We must all continue to talk about the critical problem of the nursing shortage if we are going to be able to truly offer all Americans the quality health care they deserve.

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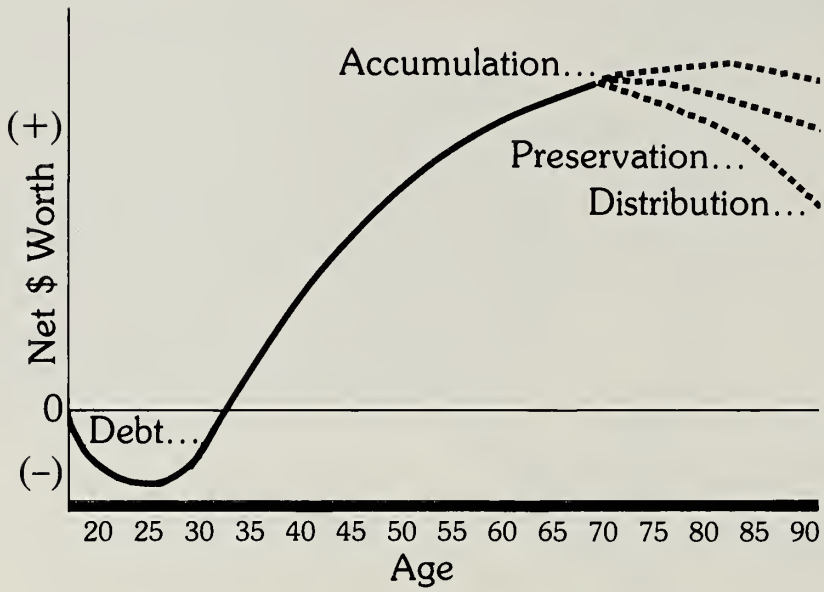

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SPECIAL REPORT:

THE STATE OF PEER REVIEW IN DELAWARE TODAY

Victor F. Battaglia, Esquire

The entire medical community has recently been confronted with a series of far reaching and serious issues and problems. Many of these could not have been imagined, much less anticipated as little as 20 years ago. Increased malpractice litigation, unprecedented and sometimes crippling insurance and litigation costs, ever increasing predominance of health care insurance, increased hospitalization and treatment costs, technology advances, governmental regulations, HMO, DRG, IPA, PRO, and so on.

Some of these are beneficial for the public, your patients, and for you. Some are merely inconvenient and some do not seem to be of benefit to anyone. No matter, there is no question that the practice of medicine is different in many ways than a generation ago.

You have been told many times, by many people, in many ways that a great many of the changes in your profession which you find distasteful (such as increased malpractice litigation, increased malpractice premiums, increased governmental regulations) are your own fault. You have been told that these things have happened or have been made necessary because of your failure to adequately or effectively police your own profession. In other words, you have been told your peer review process has failed.

Is it true? Has your peer review failed? Is some failure in the process (actual or imagined) truly the cause of any or all of these problems? I don't know. I don't think anyone does or can answer those questions.

But I think most of you would agree that peer review is necessary. Even though it may often be to some extent distasteful and time consuming, it certainly seems preferable to a more complete governmental control over your profession. There seems to be no doubt that peer review is necessary to protect not only your patients but also the very integrity of your profession. I'm sure many, if not most of you have been involved, in some way or another, with some type of peer review process of either the Medical Society, a hospital, or the Board of Medical Practice.

Peer review is essential -- and you must be involved. But there is a problem. Any person who initiates or even participates in any type of peer review procedure or investigation and any organization which sponsors peer review faces a dilemma. Hospitals, medical societies and doctors have been, and I can guarantee will continue to be sued for their peer review activities.

Allegations have been made of price fixing, defamation, restraint of trade, libel, slander, breach of contract, interference and/or destruction of business, conspiracy, and even civil rights violations.

Can you afford to conduct effective peer review with the possibility of protracted and expensive litigation hanging over your head? I think you can and I know you must try.

What you must do to engage in meaningful peer review and, at the same time, protect yourself, is to try to make sure that every possible protection from liability which the law can offer is part of the law of this State, and then be very careful that you take advantage of such protections.

I want to talk to you about the potential liability and the existing and possible protection from liability. But first there are two important factors which I believe you must consider.

Mr. Battaglia is legal counsel for the Medical Society of Delaware.

First, because of the very nature of our legal system, it is impossible for anyone to prevent someone from filing a lawsuit. There are a number of privileges and immunities from suit in the law. These exist either through traditional common law, statute, rule, or by some combination of these. They attempt to insulate to various degrees a certain status or activity but none of these can, nor I believe should, completely prevent lawsuits. A plaintiff may allege that a certain action was made in bad faith or is otherwise somehow beyond the scope of the immunity. If such can be established, then I believe the immunity would fall. Also, a suit can be filed merely for the purpose of harassment or inconvenience. Any and all such suits must be defended.

As an aside, for example, judges enjoy an absolute immunity from suit for actions taken as judges. Yet lawsuits are filed against them. (Judges also enjoy a benefit you don't. That is, the state in most cases will provide their defense.)

The important thing to keep in mind is that no matter what you or the legislature or anyone else does to protect those involved in peer review from liability -- you can be sued. What must be done is take all possible steps to make sure such suits are so unwinnable and so easily defended, that they are unattractive and unprofitable, and hopefully, very few will be filed. I will discuss some ways to do this later.

The second important thing I want you to keep in mind is that while you, or the medical societies and hospitals with which you are associated would be the defendants in any such lawsuits, it is also *you*, physicians, who would be the plaintiffs. Only physicians feel injured by peer review boards. Look around. It is your colleagues who are the potential plaintiffs. For this reason I think part of the solution must be an effort to have all practitioners involved, or at least committed to support peer review.

Perhaps the most dangerous liability exposure you could face as a result of a peer review action is under the anti-trust laws. Anti-trust litigation itself is generally complex and expensive. The law provides for treble damages to the injured party in many cases. There can be direct action by the Federal Trade Commission, administrative hearings, fines, penalties, and in some extreme cases even criminal liabilities. Fortunately, there are ways to reduce and even almost completely eliminate the impact of the anti-trust laws as they relate to the peer review process.

The anti-trust laws are designed to prohibit and penalize activities by non-governmental groups which restrain trade or have some unreasonable anti-competitive effect. The United States Supreme Court has ruled that activities of professionals constitute trade or commerce for the purpose of the anti-trust laws. Any action, then, taken by a peer review committee which in some way restricts, prohibits, or burdens a doctor's ability to practice has potential anti-trust implications. I believe concern with the anti-trust laws is much more important in the context of hospital peer review actions than of the Medical Society's committees. Obviously, a hospital committee which has the ability to restrict or deny practice or admitting privileges is more at risk in this area than the Society, whose ultimate official sanction is expulsion from the membership. This does not mean that the Society can safely ignore anti-trust implications. Even though membership in the Society is not a prerequisite for practicing medicine in Delaware, the Society's actions through some sort of disclosure, either to the public or to hospitals, or even through referral to the State Board of Medical Practice could conceivably have some actionable anti-competitive effects.

You should also be aware that under a strict interpretation of the anti-trust laws, the *motive* behind a restraint of trade is not always a defense. In other words, even if a clearly justified action results in certain types of restraint of trade, anti-trust liability could still be a problem. Some courts have held, however, that in the peer review context a patient care motive would remove peer review actions from such a *per se* liability, if the action taken is the least restrictive means to the patient-care consideration.

If, however, an anti-trust suit gets to the point of presentation of arguments and evidence with respect to patient care motives, the case has probably already become expensive. The same can be said with respect to many other aspects and defenses pertinent to an anti-trust suit. For example, to be a violation of anti-trust laws, an action must affect interstate commerce. But again, we don't want any case to get to the point of proving or disproving interstate implications. The best way to head off an anti-trust suit is for the action of peer review bodies to come under the so-called "State Action Exemption." Actions of the state government are immune from anti-trust liability. This exemption is not statutory, but is well established in judicial rulings. This rule provides that actions which result in some restraint of trade will be immune from anti-trust liability if they are taken by or pursuant to state law. There is a two part test which courts apply to determine if state action immunity applies to acts of a non-governmental body. First, the challenged restraint of trade must be clearly articulated and affirm-

atively expressed as state policy and second, the policy must be actively supervised by the State.

Unfortunately, the Federal Court for the District of Delaware has ruled that neither of these factors are present under Delaware law with respect to the actions of hospital peer review actions. Specifically, the Court ruled that the Delaware law which grants some immunities and confidentiality to peer review committee, 24 *Del. C.* Section 1768, does not constitute a "clearly articulated and affirmatively expressed state policy." Also, the Court ruled that state laws regulating hospitals do not mention peer review activities. The Court also ruled that even though the actions of the hospitals' peer review committees *could* be reported to the State Board of Medical Practice, this does not amount to active supervision by the State. While the case concerned a hospital peer review action, there is no reason to believe that the Society's peer review would be treated any differently. Under the present Delaware law, the State action exemption does not apply.

I believe that you must do whatever you can to have legislation enacted which would bring the Society's and the various hospitals' peer review committees under the protection of state law. I do not believe that merely having the Board of Medical Practice delegate peer review responsibility to such committee would be seen as an adequate articulation of the State's policy. Federal Courts have held that even if a State Board has broad authority to delegate responsibility for peer review, this would not amount to an adequate articulation of policy. While I can't predict how a court would rule with respect to a particular situation, I believe that fairly specific legislation is needed to be truly safe. Your peer review committees would need to become, in effect, an arm of the State Board. There is, of course, a price. It is that your peer review committees would have to be monitored by the State Board. Your committees would lose some of their autonomy. There would necessarily be reporting requirements, and some other inconvenient effects. But the price is small for the protections offered.

The AMA has in fact drafted model legislation to accomplish this end. I have a copy of this legislation and it has been adapted to fit Delaware's laws. I strongly recommend that this or some comparable alternative presented to the legislature.

Another somewhat similar method of finding protection from the anti-trust laws may also be available. Last year, the Federal Government passed a law which grants some anti-trust immunity to peer review bodies if their procedures follow certain due process requirements, and if they are monitored by a State Board.

This federal law, called the "Health Care Quality Improvement Act of 1986," has some rather far reaching effects in the area of reporting malpractice claims and State Board actions to a federal agency. The federal regulatory mechanisms necessary to put this law into effect are not in place mainly because the necessary appropriations have not been made. At this time, we cannot know the ultimate effect of this law and we cannot rely on its provisions. We will try to monitor this situation.

One aspect of the anti-trust problems which I have not mentioned is peer review of fees. As you know, charging excessive fees for medical services is unprofessional conduct under state law. Peer review of fees, however, is very dangerous. Price fixing is one of the *per se* violations of anti-trust law. Several of the anti-trust cases involving professionals, doctors, lawyers, or engineers, for example, involve some aspect of fee regulation.

Review of fees probably can be done, however, but only by carefully following certain guidelines. The Federal Trade Commission in response to a request from a Texas medical association has issued a set of advisory guidelines. These guidelines provide that review of fees should not be done by the regular peer review committee. Rather, a separate and independent group should conduct the review. The review must be limited to a determination of whether a charged fee is usual and customary. The review group must have no power to actually control fees or issue any type of sanctions. In effect, only a kind of advisory opinion is allowed. I feel that if a situation of excessive charges is suspected, the safest course would be a referral to the State Board.

I have another recommendation in that respect, that concerns your referrals to and the activities of the State Board of Medical Practice. As you know, the members of the State Board are volunteers who have their own professions to practice. The Board is represented by a Deputy Attorney-General who also has other duties, including the representation of other State Boards. I do not believe that the Board can function effectively in investigating and processing complaints with such part time involvement by the State. I recommend, therefore, that you consider approaching the governor and the General Assembly and propose legislation to increase your State license fees. The additional funds would be used to pay an attorney who would work for the State Board on a full time basis. With such full time participation, the Board would be much more effective in investigating complaints and referrals from the Society. The Board would also be able to process

changes much more effectively. In short, if you want more effective and widespread action, the Board needs full time help.

Let me tell you a kind of a little horror story about peer review and anti-trust litigation. In Astoria, Oregon, in the late 1970s, early 80s, a vascular surgeon named Patrick was an employee of the Astoria Clinic. He was asked to become a partner but due to salary disputes he refused and went out on his own. There is only one hospital in Astoria (population 10,000) and most of its staff are in some way associated with the clinic. Because I have already said this story involves anti-trust litigation, you can probably guess what happened next.

Patrick alleged that the Astoria Clinic essentially prevented him from practicing in Astoria. He says they stole patients, disparaged his ability as a surgeon, refused to treat his patients, etc., etc. Finally, the hospital's peer review board denied Patrick privileges ostensibly on the basis of his medical abilities. I have taken the facts of this story from the evidence presented at the trial in the Oregon Federal District Court. The results of that trial were a jury verdict of $650,000 in the anti-trust claims (multiplied by three equals $1.9 million), $20,000 in compensatory damages under state law claims, $90,000 in punitive damages, and $228,000 in attorney's fees.

Now the good news. The Ninth Circuit Court of Appeals reversed. The Appeals Court ruled that since Oregon law required hospitals to undertake peer review and also required that hospital peer review be monitored by Oregon's equivalent of a State Board of Medical Practice, the State action immunity from anti-trust applied. Further, the Court ruled that even bad faith actions by the peer review committee were protected. And there was evidence of bad faith. The Court referred to the actions of the peer review committee as "shabby, unprincipled, and unprofessional." But no liability exists under the anti-trust law. The Court did remand the case. Bad faith acts are not immune under state or common law claims. Also, there could be anti-trust liability for acts taken outside the peer review process.

It seems like a just result. The peer review process, if done in good faith, is completely protected. Anti-trust would seem not to be a problem for peer review committees in Oregon. Why did I call it a horror story? Well, for one thing, it is not over. Also, before the appeal to the Ninth Circuit, the doctors faced a liability, including attorney's fees of almost $2.5 million. Their insurer did pay their attorney's fees, but refused coverage for the liability on the ground that the defendants had, in effect, been found to have violated anti-trust laws. Wages were garnished. Several doctors reportedly were on the verge of bankruptcy. The Clinic is basically gone *and* most of the doctors have left town. Also, Patrick has appealed. The U.S. Supreme Court has decided to hear the case. Briefing is now proceeding.

This may result in a definitive ruling on the anti-trust issue as it applies to peer review activities. Hopefully, the Supreme Court will tell us how we can conduct peer review safely with the state-action immunity.

The Delaware Federal District Court case which I have referred to is not entirely dissimilar from the *Patrick* case. Allegations have been made which amount to a claim that a physician has been illegally barred from practicing at a hospital (Kent General). The Court has ruled that State-action immunity is not available. At the present time, the case is still in the very early stages. No trial date has been set and the parties are waiting for the Court to make rulings concerning some discovery and other preliminary matters. The Supreme Court's ruling in the *Patrick* case will probably have some effect on this case.

One last point with regard to anti-trust litigation. There have been several cases filed in the Federal Courts in Indiana alleging anti-trust violations by peer review committees. The courts have repeatedly held that the state-action immunity applies and have dismissed the claims. I have learned from B.J. Anderson, the AMA lawyer, that the Federal Courts in Indiana have made it clear that attorneys who file similar suits in the future face the possibility of court imposed sanctions. This is what I meant when I stated before that you must try to make such suits so unwinnable and so unattractive that few will be filed.

I would now like to talk about the protection which current law offers to the peer review process. Section 1768 of Title 24 of the Delaware Code states, in part:

> **Section 1768. Immunity of persons reviewing medical records, medical care and physicians' work**
>
> (a) The Board of Medical Practice, the Medical Society of Delaware, their members, or the members of any committees appointed thereby, and members of hospital and osteopathic medical committees, ...shall not be subject to, and shall be immune from, claim, suit, liability, damages, or any other recourse, civil or criminal, arising from any act or proceeding, decision or determination undertaken or performed or recommendation made so long as such member acted in

> good faith and without malice in carrying out the responsibilities, authority, duties, powers and privileges...

The statute also makes the records and proceedings of such committees confidential.

This statute seems clear and comprehensive. But several recent court decisions have eroded, at least insofar as its confidentiality provisions, the statute's effect. As yet there has been no direct challenge to the immunity provision which resulted in a definitive judicial determination of the scope of the immunity.

Almost three years ago in a case which has received a significant amount of notoriety both within and without the medical community, the Delaware Supreme Court stated with respect to the confidentiality privilege of this statute:

> Privileges are repugnant to the adversarial judicial system in the United States and are therefore narrowly construed.

Then citing as authority a quite famous 1974 United States Supreme Court case dealing with privileges, *U.S. v Nixon*, our Supreme Court went on to state:

> The need to develop relevant facts is fundamental in an adversarial system. The integrity of our system relies on full disclosure of all relevant facts within the framework of the Rules of Evidence.... These exceptions are not lightly created nor expansively construed for they are in derogation of the search for truth.

With these statements as background, the court then ruled that the statute protects only the records, proceedings, and testimony of and before the committee. Any document disclosed to non-committee members loses the privilege. For an example, findings or conclusions of a hospital peer review body which are sent to department heads who are not on the committee are no longer privileged. The deliberations of the committee which led to such conclusions, however, remain privileged. The court did rule that such waiver of privilege by publication does not affect the immunity of the committees' members.

With respect to the privilege provided to those who offer testimony before a peer review committee, the Court ruled that that witness may not be questioned in any subsequent proceeding with respect to the sum and substance of his testimony. He can be questioned regarding the events about which he testified. In other words, the witness cannot be asked, "What did you say to the committee about such and such?" He can be asked, "What do you know about such and such?" The events as to which a committee conducts a hearing do not become privileged simply because the committee holds a hearing.

Also not privileged are the identities of witnesses, the times and places the committee met and other nontestimonial information. Much of the court's rulings are based on the Court's feeling that the committee's proceedings must be open to investigation to some extent so that possible bad faith or malicious actions are not insulated.

Also keep in mind that things such as informal investigation by committee members which are not authorized by the committee, discussions in hallways, etc., are not privileged. You must be careful to keep committee business within the closed doors of committee meetings.

In another recent Superior Court case, the Court ruled that the confidentiality privilege granted by Section 1768 falls if the committee does not follow the procedures set forth in the organization's by-laws for taking peer review actions. This case concerned a hospital's suspending or terminating a physician's privileges. The message here is that in taking any kind of peer review action you must be careful to follow the procedures outlined in the Society's or a hospital's by-laws. Also, several Federal Courts (including Delaware's) have ruled that peer review confidentiality does not exist when a Federal anti-trust action is brought.

A final word -- insurance. I am confident that most of you have some coverage for your peer review activities. PHICO policies provide coverage for acts you take as a member of a formal peer review or accreditation committee as long as you are acting within the scope of your duties on that committee. Likewise, the Society's PHICO policies provide similar coverage and I believe the hospitals also have policies with comparable provisions.

However, it has been ruled to be against public policy for an insurer to provide coverage for anti-trust awards. And, in fact, most policies provide a specific exclusion from such coverage. The State Society's PHICO policy does provide, however, for defense costs in an anti-trust action. I assume individuals' policies have similar provisions.

Also, as you all are probably aware few, if any, insurers provide coverage for punitive damage awards. In short, you are most probably covered for defense costs but there is a distinct danger that you would not be completely covered for *all* damage award.

In closing, you can minimize your potential liabilities in participating in peer review. You must follow closely the rules and by-laws of the peer review body. But I believe you won't be safe until there is legislation which makes clear that peer review committees of hospitals and the Society are state actions so that the danger of these types of suits are reduced to a bare minimum.

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View Box

John S. Wills, M.D., View Box Editor

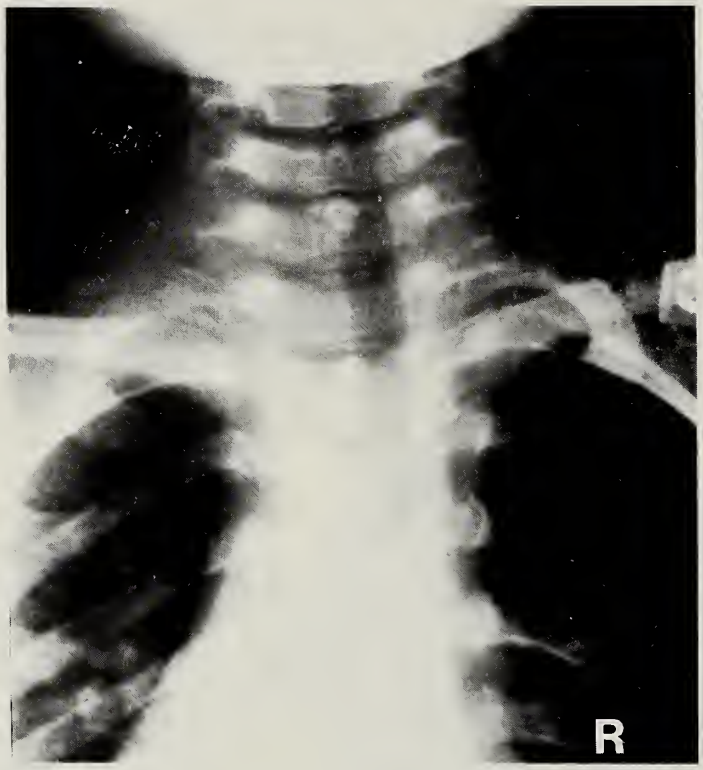
INTERMITTENT TORTICOLLIS

Leslie E. Grissom, M.D.

This 4 1/2 year old boy has been followed since infancy for intermittent torticollis occurring at the time of upper respiratory infections. The physical examination was normal in the intervals between infections, but shows torticollis with tightness of the right sternocleidomastoid muscle at the time of the infection. The symptoms have improved with age.

WHAT IS YOUR DIAGNOSIS?

Dr. Grissom is a radiologist in the Department of Medical Imaging at the Alfred I. duPont Institute in Wilmington.



Intervertebral disc calcification

AP and lateral views of the cervical spine show calcifications of the intervertebral discs at C5-C6, C6-C7, T1-T2, and T2-T3, with anterior protrusion of the calcification at C5-C6. The soft tissues and bony structures are otherwise normal. Review of previous examinations shows similar findings, although the calcifications were not as well defined.

Calcification of the intervertebral discs in children is a different entity from that seen in adults. In the latter, the calcifications are permanent and are located in the annulus fibrosus, most often in the thoracic and lumbar areas. They are felt to be an asymptomatic manifestation of degenerative disease. Metabolic diseases such as ochronosis or hemochromotosis can also cause calcifications in adults.

In the pediatric patient, the calcifications occur in the nucleus pulposus. The etiology is unknown, but metastatic infective processes or trauma have been implicated because of their frequent clinical association. The calcifications most often occur in the cervical region (60-82%), and when they do, are usually accompanied by symptoms such as neck pain, torticollis, fever, and limited range of motion, as well as the history of repeated upper respiratory infection or trauma. The calcified discs often protrude (30%), usually anteriorly. Rarely, they cause nerve root or spinal cord compression which may require surgery. The cervical calcifications usually resorb within weeks to months with resolution of the symptoms, but can persist, as they did in this patient. Although there are seldom long term sequelae, mild degenerative changes have been reported. Because of the self-limited nature of the disease, conservative treatment is recommended. Calcifications in the thoracic and lumbar areas vary from the cervical calcifications in that they are most often incidental findings in asymptomatic patients, and are usually permanent.

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Medical Ethics

This has been taken from the *Current Opinions of the Council on Ethical and Judicial Affairs of the American Medical Association*, and is provided as a service by the *Ethics Committee of the Medical Society of Delaware, Robert W. Frelick, M.D., Chairman.*

5.05 CONFIDENTIALITY

The information disclosed to a physician during the course of the relationship between physician and patient is confidential to the greatest possible degree. The patient should feel free to make a full disclosure of information to the physician in order that the physician may most effectively provide needed services. The patient should be able to make this disclosure with the knowledge that the physician will respect the confidential nature of the communication. The physician should not reveal confidential communications or information without the express consent of the patient, unless required to do so by law.

The obligation to safeguard patient confidences is subject to certain exceptions which are ethically and legally justified because of overriding social considerations. Where a patient threatens to inflict serious bodily harm to another person and there is a reasonable probability that the patient may carry out the threat, the physician should take reasonable precautions for the protection of the intended victim, including notification of law enforcement authorities. Also, communicable diseases, gun shot and knife wounds, should be reported as required by applicable statutes or ordinances. (IV)*

*These citations refer to the *Principles of Medical Ethics* which may be found in the rear of the 1987-88 *Pictorial Roster* of the Medical Society of Delaware.

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Editorials

Members of the Medical Society of Delaware are invited to submit material. Preferred length is approximately 250-500 words. For further information contact the Journal office, 658-3957.

THE PENDULUM'S ARC: A LESSON FOR TODAY'S PHYSICIAN

One of the things we physicians never seem to have time to do is to sit and do nothing at all but let our minds wander. We are made to feel guilty if we are not doing something physically productive, and that we are wasting our time. Psychiatrists tell us that watching tropical fish, while nonproductive of a material end product, is good, because it is relaxing and allows the mind to freely wander.

One other similarly relaxing activity I recently found was watching a clock pendulum. To the uninitiated, a pendulum is merely a weighted rod swinging back and forth in a gentle arc. As may be recalled from undergraduate physics class, the movement is actually the sum of multiple forces, all moving perpendicular to the rod, which somehow, and I frankly have forgotten how it all works, winds up moving the weight in an arc. What is important in this observation is that despite multiple forces all pulling in slightly different directions, the pendulum moves smoothly through space.

We physicians are somewhat like that pendulum. We each move in a slightly different direction in our practice lives, no two in the same exact path, yet ideally, like the pendulum, our pooled individual efforts culminate in today's medicine. Cute, but not very deep, you say? Better get back to seeing patients, you say? But there is more to this story, of course. Think back to Physics 101. Resisting this gentle, smooth motion are forces which serve to stop the pendulum: gravity, air resistance, and maybe the most important, internal friction.

While we all seem to band together to oppose the external forces operating upon us reasonably well, it is the internal forces that we have the most difficulty overcoming. It is no secret that over time the external forces have increased, determined to modify the movement of medical care; as a group, we have generally responded well and with uniform effort to protect the delicate balances which represent today's high level of medical care. What is surely driving the mechanism to a halt is the developing internal friction between us.

While backslapping each other at society meetings, at conferences, at restaurants and clubs, simultaneous backstabbing is heard in the hallways and lounges, such as, "He's not good enough to join our staff," "He's a second class doctor," or "We need to close our staff because there's already too many in our department."

While short sighted efforts to protect our little force on the movement of the medical pendulum may seem prudent, it behooves all physicians to avoid false beliefs in the magnitude of their own tiny force in the course of medicine. Nor should we believe in perpetual motion machines, that a fixed force, refusing to add the energies of others, will continue unabated. We cannot naively believe that the pendulum will move on forever unless each of us does his part to ensure the reduction of internal friction, so that the contribution of all of the individual forces will continue the movement of medicine across time.

Edward R. Sobel, D.O.

INTEGRATING THE DELAWARE HOSPITAL: DOES ANYONE REMEMBER?

I recently spent a few interesting hours reading a book which deals in large part with the care, or lack of it, of black citizens, particularly in the South.[1] The author, while giving the history of their fight to gain access to health care facilities, hospitals, medical schools, residencies, and professional societies, makes an interesting observation that many of us can corroborate. Unlike the integration of restaurants, public schools and universities, the integration of hospitals was accomplished for the most part without fanfare and without public demonstrations. How did this come about?

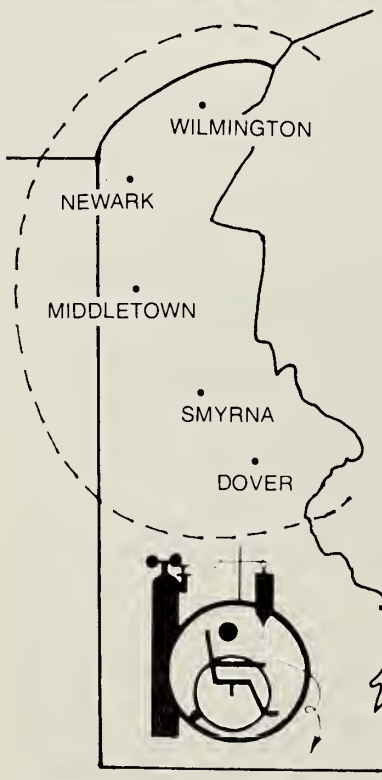
There are two things I remember about the then Delaware Hospital the day I drove down from Philadelphia to Wilmington in early 1951 to apply for an internship. To a medical student on a budget, the free lunch at the Tumor Conference I attended seemed generous, especially the basket of fruit. And the bathrooms were segregated, something I had read about but never experienced.

After driving from Philadelphia (I-95 had not yet been invented, and Chester seemed a large city, Philadelphia-sized, or larger), I needed to freshen up before my interview. To my enduring surprise, I was confronted with a door which said WOMEN WHITE. In innocence or ignorance, I took this to mean that that bathroom was not for me until next year if I returned as an interne, being reserved for nurses, lab techs, and women physicians if there were any: ie, women in white. What a surprise: the next door said WOMEN COLORED.

While I was an interne in '51-'52, and then a resident (internal medicine, three years) there was a separate Colored Ward which housed both men and women. Sometime in the late 50s or early 60s, I do not remember when or why, the colored wards on the fifth floor disappeared in favor of a men's ward, no color stipulated, and a women's ward, ditto.

I was reminded of their passing recently when the Wilmington Hospital was renovated. The last vestiges of multi-bed wards are gone, except for the most costly rooms in the house: ie, the ICUs. The curious and wonderful thing is that although I have spent time at that hospital (Delaware Hospital, then Delaware Division, now Wilmington Hospital) almost daily except for vacations since July of '51, I do not remember the transition to integration except for a few anecdotes.

The drinking fountains were also separate then as well as the bathrooms. Doing away with the second floor set of lavatories for "colored," provided the room needed for



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the construction of the audiology suite, still in that site, and the extra drinking fountain went at the same time. But for a short while, taking a drink or going to urinate were segregated activities on the first floor but not on the second. I remember seeing two policemen, one white and one black, walking together on the first floor, and realizing that on that floor they would need to separate to visit the facilities, but could go together on the next.

It speaks very well of Delaware's medical community that the integration of all the clinical services at the Delaware Hospital went so smoothly and inconspicuously. To whose leadership is this a credit? Was it achieved in some special way? Who took the initiative, and why at that moment? Was it done similarly or even simultaneously at the other hospitals in Wilmington? What about open membership in the Medical Society of Delaware?

I would like to hear from anyone reading this who remembers how integration came about in the hospitals and medical societies of Delaware. It is an historical period that bears chronicling before those who could write the chronicle have passed on to Heaven, which if there really is one, is presumably also by now a totally integrated facility.

Bernadine Z. Paulshock, M.D.

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ON THE DIAGNOSIS AND PREVENTION OF BILATERAL GLUTEAL HYPERMALACIA ATROPHICANS SYNDROME (OR GALLUP POLL DISEASE)

Each year, we pediatricians go through the ritual of performing school and college physical examinations. What I have noticed with increased frequency is that my patients are getting less fit and softer and flabbier by leaps and bounds. Up to 50% do not get enough exercise to develop healthy hearts and lungs, and many cannot pass a standard test for physical fitness. Forty percent of five-to-eight year old children show at least one risk factor for heart disease such as elevated blood pressure, high cholesterol, or physical inactivity.

Some school children get as little as one hour of physical education each week. In addition, schools traditionally have emphasized sports that promote agility and skill and not necessarily cardiovascular fitness, just as if we are supposed to bring up endless generations of football players.

Television is also part of the problem; current appalling statistics state that American children sit on their butts as much as 25 hours per week watching the tube.

Children in Delaware need to shape up, and they need your help. The American Academy of Pediatricians has released a statement on fitness which urges schools to maintain, if not increase, their physical education programs.

What can you, as a physician, do? First, make your adult patients aware that their children may be spending too much time watching TV, and that it is their responsibility as parents to monitor and budget the time their children watch television. Second, urge them to write to their school boards asking them to increase physical education in schools. Suggest that introduction of the innovative idea of including activities that teach a lifetime habit of aerobic exercise such as tennis, swimming, running, power walking, and bicycling. Remind them that even children who are not jocks deserve a healthier cardiovascular future.

Parents should also promote fitness at home by staying fit and talking about it.

I am sure that when these children become adults, they will one day come back to say thank you. (I hope.)

Maurice Liebesman, M.D.

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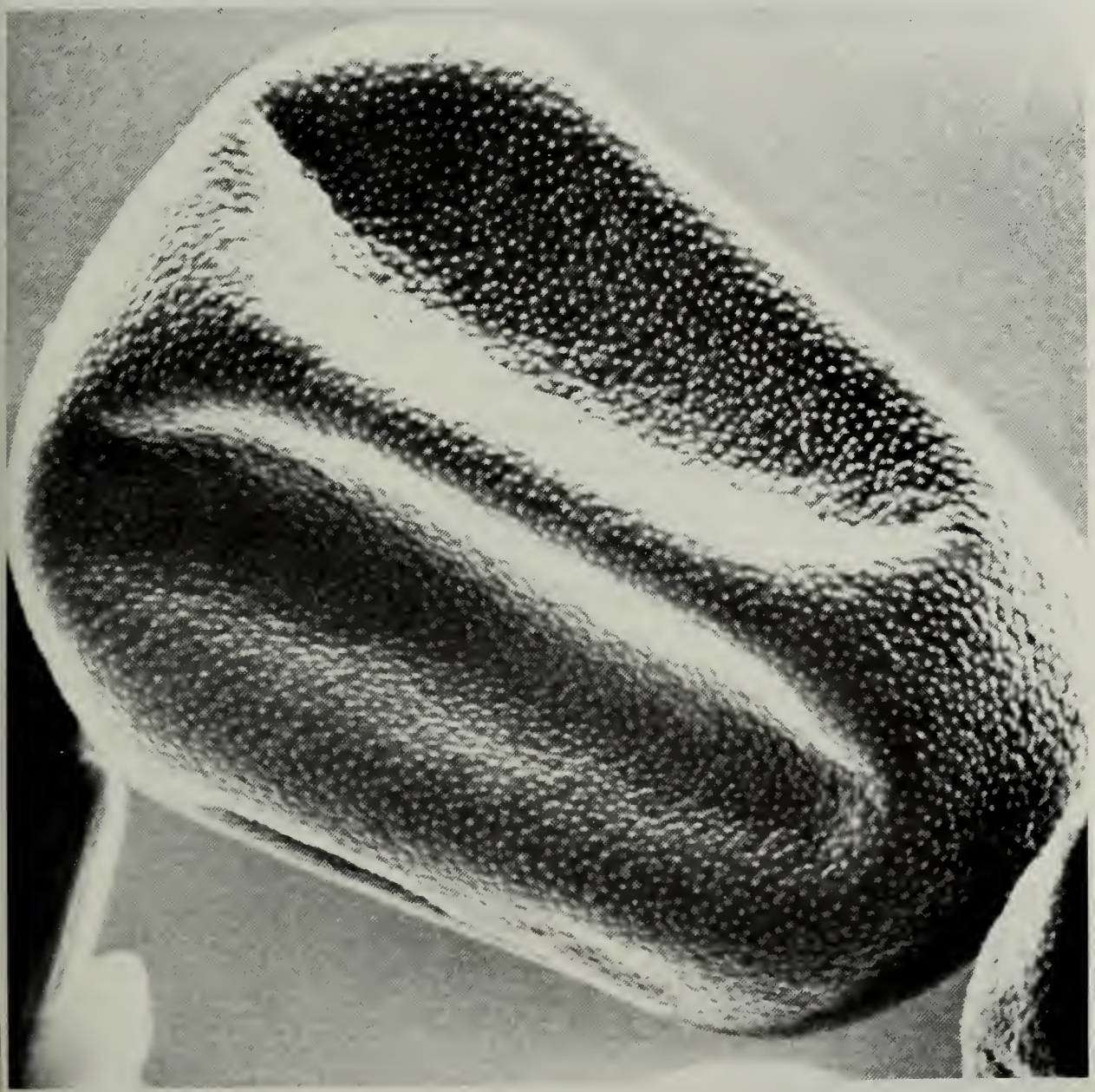
In Black and White

Dennis R. Witmer, M.D. Photographic Editor



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— Contributed by Leonard H. Seltzer, M.D.

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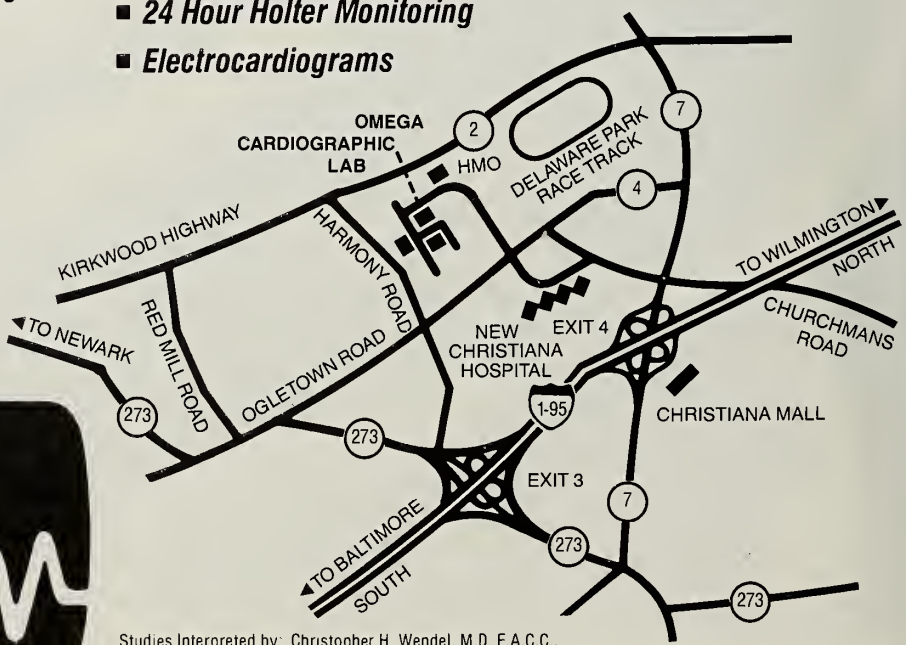

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Letters To The Editor

ISN'T SOMETHING MISSING?

To the Editor:

The case history (Delaware Medical Journal, 1987; 59(11):725-727) written by Drs. Marc D. Feldman, William P. Butler and Lester Dunmire, all physicians, is quite intriguing as the history of the loss and recovery of a foreign body. What is equally interesting is that the psychosocial history remains totally lost.

Well, not really. The authors do acknowledge that the patient's accident at the age of 13 was "bizarre": "She jumped from a windowsill, impaling herself with a pool cue stick. The cue stick entered the perineum just posterior to the vagina, penetrating into the abdomen." This is indeed bizarre. The clues are that this is a severely psychosexually disturbed adolescent.

Further indication of the lack of medical intervention, either physical or mental, is that she presented at 16 years old pregnant. Again, a strong clue to significant disturbance in the psychosocial and psychosexual spheres.

While it is apparently true, as the authors indicate, that "impalement injuries are unusual causes of abdominal trauma, scarcely referenced in the literature," psychosexual and psychosocial disturbances are really quite well referenced. I therefore draw the conclusion that in addition to the inadequate abdominal exploration at the time of the original injury (they couldn't have done a CT scan of the original injury three years earlier? Maybe they didn't have the instrument yet?), there could also have been significant psychosocial intervention at that time.

Whereas Dr. Graff's editorial about the return of psychiatry to medicine in the same issue addressed problems from the psychiatric side, this article demonstrates problems from the side of other physicians. The omission is so glaring as to be truly infuriating, an example of out of sight out of mind.

I would reiterate the remarks of Dr. Coggins in the closing paragraph of his review of his year as president of the Medical Society: "We must guard against increasing self-centeredness in a profession that is basically egocentric and think more of a collective protectionism that fosters increased socialization." That increased socialization should include a great deal of consultation and meetings where psychiatrists, surgeons, and internists meet together to improve patient care. It is in this manner that we shall all become better physicians, get better patient results, and significantly reduce both frivolous and real malpractice cases.

Leon Morton Green, M.D.

DELAWARE IS IN TOUCH

To the Editor:

"In Touch" is a free telephone system for teenagers, young adults, their parents, and professionals who work with youth. There are currently 50 messages available for listening. These messages cover a variety of topics, including sexuality, puberty, signs and symptoms of pregnancy, AIDS, abstinence, myths about sex, family planning services, super performance tips for athletes, homosexuality, and sexually transmitted diseases. The messages range in length from three to five minutes.

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Lucille P. Siegel, M.P.H.
Director
Office of Adolescent Health Services

DR. ALBERT OTTOW: MASTERFUL INACTIVITY AND DYING WITH DIGNITY

To the Editor:

Recently, Dr. Albert Ottow, a retired physician with 53 years of active practice behind him, died at the VA Nursing Home near Elsmere. Sometime in his active practice or during his 15 years of retirement he penned the following statement and distributed it to his family. His daughter has given me permission to share it with you.

* * *

When Dr. Will Mayo was dying of stomach cancer, he became jaundiced. He diagnosed it at once as metastasis of cancer to his liver. "It has blocked off the duct," he reported in a matter-of-fact tone. "This is it." He received one pint of blood, which was the only transfusion he accepted. He could have been kept alive for a time with constant transfusions and intravenous feedings, but it wasn't his style. His instructions were, "I've had a good life, and this is all right. But I'm not going to have any further medication to keep me going--no more intravenous, nothing except some morphine for the pain." I greatly admire the style of his death, putting aside the oxygen tent, intravenous feedings, and medications to prolong death, and deciding to die when it was time. This acceptance is stamped with dignity, a quick conscience, a sense of fitness.

In recent years, medicine has advanced greatly in technique for maintaining some kind of life in the dying for years at a time. I think that we have gone too far in this direction. We should keep people going only as long as it is possible to restore them to a sane, conscious degree of health. It is a tragedy to maintain life as an unconscious vegetable, but it is happening in every hospital in the land; it drains the families economically and emotionally, and serves no purpose that I can respect.

A doctor cannot act as God, nor should he attempt to make life and death decisions on his own, but he can consult with his colleagues and perhaps with others, clergymen, for example, in order to decide that the time has come to discontinue intravenous feeding and let the patient go naturally. I call this "masterful inactivity," and I have made it clear to all those near me that I want it practiced on me, when the time comes.

* * *

Physicians have taken the lead in saving countless lives and restoring them to health and happiness through our new drugs, surgeries, and diagnostic discoveries. The side reaction is that we also often prolong the process of dying in some to the detriment of the patient, his family, and the hospital. We are being blamed for this and not unreasonably so. We should take the lead in solving this problem which is growing larger with each new death-deferring discovery.

William T. Hall, M.D.

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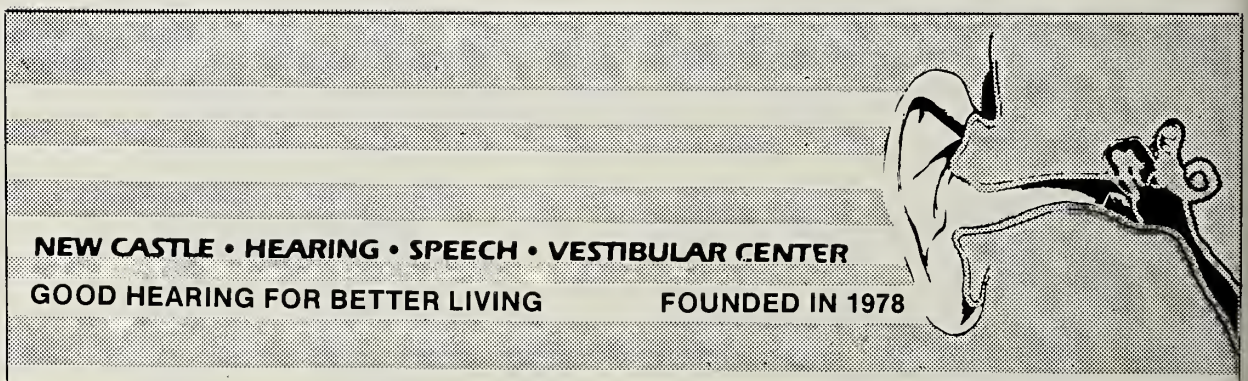

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DEATHS

WALTER L. BAILEY, M.D.

Dr. Walter L. Bailey, an orthopedic surgeon who practiced in Wilmington for many years, died March 5, 1988 of heart failure in Vero Beach, Florida. He was 72.

Dr. Bailey was a graduate of University of Indiana, and graduated from the University of Maryland School of Medicine in 1940. He was a colonel in the Army Medical Corps, serving in the European Theater during World War II. Upon his return, he took his orthopedic residency at St. Luke's Hospital in New York City.

He opened a practice in orthopedic surgery in Wilmington in 1949, where he practiced until his retirement in 1980. He moved to Florida in 1981. During his career, Dr. Bailey was a consultant at Delaware State Hospital. He was a member of the American Academy of Orthopedic Surgeons, the Association of Bone and Joint Surgeons, the American Medical Association, the Medical Society of Delaware, and the New Castle County Medical Society. Dr. Bailey helped to pay for his medical educational expenses by playing the trumpet, and played with the Dorsey Brothers. In later years, he was a member of the Dixieland Doctors.

HARRY A. CARL. M.D.

Dr. Harry A. Carl, a New Castle family practitioner for more than 40 years, died of congestive heart failure March 17, 1988. He was 77.

Dr. Carl did undergraduate work at Pennsylvania State University and graduated from Susquehanna University in Selinsgrove, Pennsylvania. He was a 1937 graduate of Hahnemann University School of Medicine, and did his internship at Memorial Hospital in Wilmington, serving on staff there and subsequently at the Wilmington Medical Center for 50 years. Dr. Carl practiced family medicine in New Castle from 1941 until ill health forced him to retire in 1985. During his career, he was a medical adviser to New Castle County Draft Board 1 for more than 25 years.

He was a fellow of the American Academy of Family Physicians, a past president of the Homeopathic Medical Society, and a member of the American Medical Association, the Medical Society of Delaware, and the New Castle County Medical Society.

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1. A. Morales et al., New England Journal of Medicine: 1221. November 12, 1981.
2. Goodman, Gilman — The Pharmacological basis of Therapeutics 6th ed., p. 176-188. McMillan December Rev. 1/85.
3. Weekly Urological Clinical letter, 27:2, July 4, 1983.
4. A. Morales et al., The Journal of Urology 128: 45-47, 1982.

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Book Reviews

William L. Jaffee, M.D., Book Review Editor

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ANNUAL REVIEW OF IMMUNOLOGY: VOLUME 5, 1987, edited by **William E. Paul, C. Garrison Hathman,** and **Henry Metzger.** 1987; Los Angeles, Annual Reviews, Inc. 690 pp. Price: $35.00.

There are 24 extensive review articles in this book which cover various areas of research in the field of immunology. The reviews were written, at the request of the editorial board, by prominent investigators currently engaged in the appropriate area of research. In most cases the authors present a historical approach with an expansive literature review (80-150 references per article) of their specific interests. They describe experiments performed by their own laboratories, correlating them with the work of others, usually chronologically.

Most of the articles are well written, but are difficult to read quickly as they have no abstract, few have summary sections, and all delve deeply into the technical aspects of the particular model. This series would be of great interest to those engaged in basic research in immunology, and to clinical immunologists and rheumatologists interested in the underlying mechanisms of cellular interaction and regulation during an immune response or autoimmune state. There are no articles which deal specifically with AIDS, but many of the immunologic principles inherent to the pathophysiology and epidemiology of AIDS are well elucidated in the review on virus-introduced immunosuppression from the Scripps Clinic and Research Foundation. This clinical review should be read by anyone interested in the pathogenesis of AIDS.

The volume should serve as a good reference source for investigators in the field, and for students and practicing physicians interested in the basic science of immunology.

Mark A. Marsili, Ph.D.

Dr. Marsili is a third year student at Jefferson Medical College.

DUBOIS' LUPUS ERYTHEMATOSUS, edited by **Daniel J. Wallace, M.D. and Edmund L. Dubois, M.D.** Philadelphia, Lea & Febiger. 1987. Price: $98.00.

Dr. Edmund Dubois, who died in 1985, was a clinician and investigator whose work contributed greatly to our understanding of systemic lupus erythematosus. His clinical investigation firmly established the role of antimalarial therapy in the treatment of lupus, and his laboratory investigation helped to develop the New Zealand mouse model for lupus. Among his clinical contributions was the first description of avascular necrosis of bone in lupus, peptic ulceration as a complication of steroid use in lupus, the development of lupus subsets, and the treatment of cerebritis and hemolytic anemia. He helped to develop one of the largest clinical centers for the study of lupus in the world and is said to have followed 500 lupus patients in his private practice.

Since the last edition was published in 1976, a good deal of information has evolved regarding our understanding of basic pathophysiology and immunology and this is reflected in large sections of the text. The contributing authors are extremely well known figures in rheumatology in their own right. The review of clinical manifestations has been largely written by Dr.

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Dubois. The text is eminently readable, inclusive, and annotated. The figures are good and photographs are well replicated. One interesting aspect of the book is the historical perspective given to many topics that are discussed.

In summary, this is a text that combines a thorough review of the basic physiology of lupus with an extensive review of the clinical characteristics of the disease. In particular, it depends on a wealth of clinical experience encountered by one man over a lifetime of treating lupus. It is an excellent source of information.

James H. Newman, M.D.

SJOGREN'S SYNDROME, edited by **N. Talal, M.D., M.H. Moutsopolous, M.D.,** and **S.S. Massan, M.D.** New York; Springer-Verlag. 1987. 300 pages. Price $100.

This 300 page textbook details the current knowledge regarding Sjogren's syndrome. Introductory chapters deal with historical aspects of this fascinating syndrome, including a chapter discussing the patient's perspective.

Clinical characteristics are discussed in some detail, including glandular and extraglandular manifestations of the disease. There are chapters on oral and ophthalmologic manifestations of Sjogren's as well as a discussion of the chemistry of saliva and the histopathology of the syndrome. International aspects of the disease are included with a review of primary Sjogren's syndrome in the People's Republic of China. Neuromuscular manifestations (which are common and

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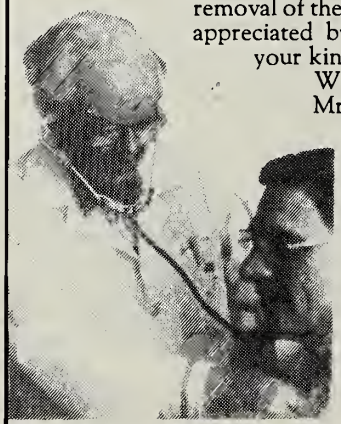

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important), respiratory complications, gastrointestinal features, renal disease, and vasculitis are each handled in turn.

There are several chapters detailing the relationship between the emergence of lymphoproliferative disease and malignancy in these patients. There is also a section in this text discussing interrelations of Sjogren's syndrome with other autoimmune diseases.

The concluding chapters of the book deal with the laboratory manifestations of Sjogren's syndrome and finally, with its treatment. Unfortunately, this is a particularly short chapter, since treatment is purely symptomatic, combined with the avoidance of those factors which can worsen symptoms.

All in all, I would recommend this text to dentists, otolaryngologists, rheumatologists, and any physician who is interested in this fascinating connective tissue disease.

James H. Newman, M.D.

THE PRACTICING PHYSICIAN'S APPROACH TO HEADACHE, FOURTH EDITION, edited by **Seymour Diamond, M.D.** and **Donald J. Dalessio, M.D.** Baltimore; Williams and Wilkins. 240 pages. Price $ 38.50.

Headache is one of the most common presenting complaints, and one of the most frustrating problems to treat given the lack of clear clinical findings and widely variable responses to treatment. This book addresses the physician's desire for practical information on the diagnosis and treatment of headache disorders.

Much of the information on the approach to the various causes of headache comes from the vast clinical experience at Dr. Diamond's headache clinic in Chicago. He is quick to admit that many of the treatment regimens proposed are empiric, but have proven to be effective in his years of practice. He stresses the need to accurately diagnose each patient's headache because of the different treatments of various headache types.

The writing is clear, and specific recommendations are given for both diagnosis and treatment of the various disorders. A vast number of references are cited, and theory is separated from proven fact. In addition to pharmacologic and surgical treatment of headache disorders, the authors discuss the role of acupuncture and biofeedback in the treatment of muscle contraction and mixed headaches. A final chapter describes the approach to diagnosis and treatment of difficult headache patients in the author's own clinic.

Information on headache disorders can be found in books of different disciplines, including neurology, medicine, psychiatry, ophthalmology, and otolaryngology. This book presents a multidisciplinary approach to headache and contains all the information needed by the average practitioner to more effectively diagnose and treat the next headache patient who walks in the door. I recommend it to everyone who deals with this universal problem.

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SECTIONAL HUMAN ANATOMY, by **Man-Chung Han** and **Cho-Wan Kim.** New York; Igaku-Shoin Publishers. 1985.

The conventional teaching of anatomy to medical students has been disrupted by the advent of computer tomography, ultrasound, and magnetic resonance imaging. It is now necessary to teach anatomy so that the axial images of these new modalities can be understood. These thoughts are echoed in the opening paragraph of the preface of this new atlas. There have been other cross-sectional atlases before, but their format has differed, not all include MR images, and they have been directed at a special readership. This atlas purports to be for medical students, residents, radiologists, surgeons, and internists. It is an attractive, large format book and as expected, has its advantages and deficiencies. The criticisms predominate, although ultimately they may not detract from the usefulness of the text.

The basic format of the text is colored plates of transverse, coronal, or sagittal sections of a cadaver injected with red and blue dye to delineate vascular structures. The quality of the cadaver plates is excellent, both in demonstrating anatomy and in photographic reproduction. Generally, the corresponding images are on the facing page, oriented identically, with two to three letter abbreviations placed directly on the image over a particular organ or area. The same abbreviations appear on the cadaver sections. This is a useful format, far more so than rather cumbersome methods of having lines radiating from an organ to a peripheral area of the page

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with the name of the structure written in full. It is also better than having organs numbered with a key at the bottom of the page. In this atlas you can look directly at the area and the code letters, and it is usually clear what you are looking at. For example, *XP* stands for xyphoid process, *SC*, spinal cord, etc. Abbreviations are unique to an organ, so there is no ambiguity. In other words, *Sp* means spinalis muscle, *Spl* means spleen, and *SC* means spinal cord. This is a useful and efficient system. At the bottom of each pair of plates there is a legend of abbreviations pertinent to each area as well as a schematic diagram of a torso with the position of each section indicated.

The organization of the atlas suffers in comparison. Extremities are not included. There are no ultrasound images. Some plates are oriented vertically on a page, whereas in another section they may be horizontal. Consistency in orientation is important in allowing the mind to visualize three dimensional concepts and the erratic format undermines this. The magnetic resonance images are all alone in a section without corresponding anatomic sections. Only two coronal chest MR cuts are given. No coronal MR abdomens are shown. Only two sagittal MR pelvis sections are included. No sagittal head MR images are present, an oversight which is hard to understand. There is an entire chapter of exceptional sagittal anatomic sections of the abdomen with no facing MR or CT image.

MR and CT images of the head are in different sections, so one cannot compare areas of corresponding interest without flipping back and forth to different sections of the book. Two technical considerations: the MR images are not state-of-the-art in quality, and all sections are obtained with the same spin-echo technique.

There are several other disadvantages. The lower neck and superior mediastinum are inadequately shown on axial CT images. Areas which may be labelled on an anatomic specimen section are not always labelled on a corresponding image. Certain areas are poorly demarcated, for example, anatomic spaces, such as the lesser sac, are not well marked. The index is adequate, with each entry given in English, Chinese, and Korean along with its abbreviations and page number.

Despite the drawbacks, this is a useful book. If the negative aspects were to be rectified, it would be a superior atlas. Its deficiencies are not so much what is presented but inconsistencies of format and incompleteness. An improved version of this book would be valuable for all the practitioners mentioned in its preface.

Joseph M. Ullman, M.D.

Dr. Ullman is a fourth year resident in the Department of Radiology at The Medical Center of Delaware.

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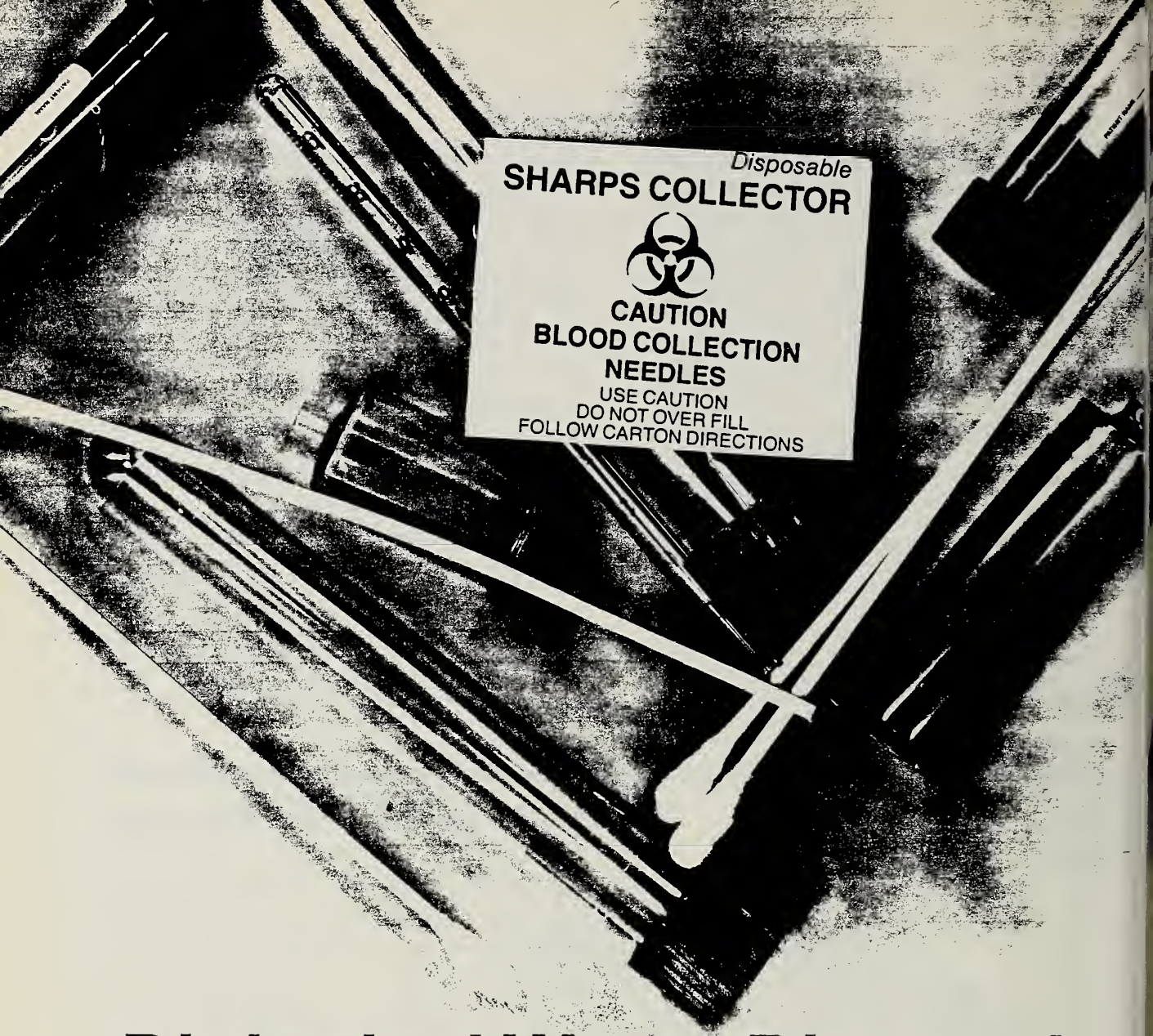

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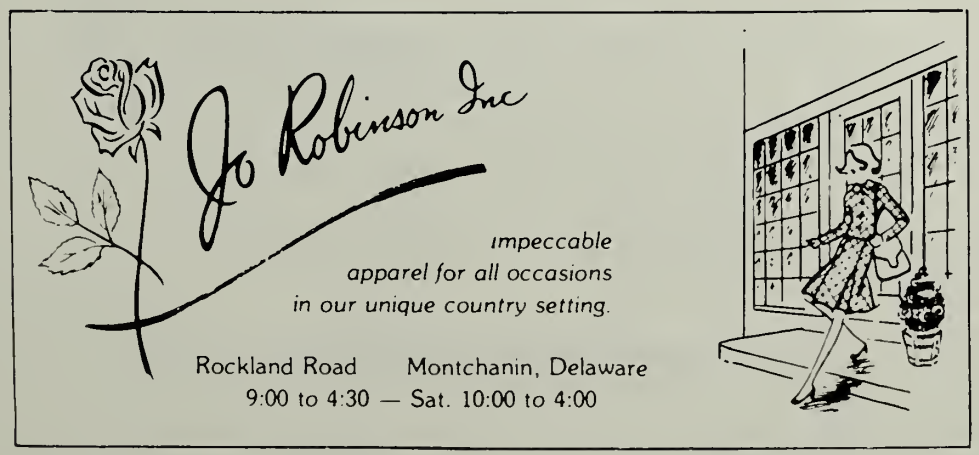
CLINICAL MEETINGS AND NOTICES

INFECTIOUS DISEASE SYMPOSIUM

The 25th Annual Infectious Disease Symposium will be held May 2-6, 1988, at the Delaware Academy of Medicine Building. For more information, contact Dr. William J. Holloway, Infectious Disease Research, The Medical Center of Delaware, PO Box 1668, Wilmington, Delaware, 19899, or call 302-428-2744.

COMPUTER APPLICATIONS IN RADIOLOGY

Hilton Head Island will be the site of the Ninth Conference on Computer Applications in Radiology on June 1-4, 1988. This course has been accredited for up to 21 hours in Category I of the AMA. For more information, contact Janice Ford, Continuing Education Coordinator, Department of Radiology, Hospital of the University of Pennsylvania, 3400 Spruce Street, Philadelphia, Pennsylvania, 19104, or call 215-662-6904.



DELAWARE CHAPTER AMERICAN ACADEMY OF PEDIATRICS

The Delaware Chapter of the American Academy of Pediatrics will hold their Annual Meeting May 25, 1988 at 7:30 p.m., at the Delaware Academy of Medicine Building in Wilmington. There will be no fee for attendance at this meeting. The key speakers will be Dr. Joel Klein and Dr. Steven Epps, speaking on, "Everything You Always Wanted to Know About AIDS But Were Afraid to Ask." There will be a question and answer period following. One hour of Category 1 CME Credit has been applied for. For more information, call Dr. Maurice Liebesman at 762-6222.

40TH ANNUAL FAMILY PHYSICIAN MEETING IN MARYLAND

Celebrating 40 years of "Care with Caring," the Maryland Academy of Family Physicians will hold its Annual Meeting and Scientific Sessions Wednesday through Sunday, May 11-15, 1988, at the Sheraton Fountainebleau Inn and Spa in Ocean City, Maryland. The program meets the criteria for up to 32.75 prescribed credit hours from the American Academy of Family Physicians, and up to 32.75 Category 1 hours from the AMA. Among the many meetings and lectures, the popular Cardiovascular Round Table will again be held. Pre-registration before May 8, 1988 is urged. For more information, write the Maryland Academy of Family Physicians, 5700 Executive Drive, Suite 110, Baltimore, Maryland, 21228. Reservations to the Sheraton may be made directly by calling 800-638-2100.

BERKSHIRE AREA HEALTH EDUCATION CENTER

The Fourth Annual Berkshire Medical Conference, co-sponsored by University of Massachusetts Medical School, Berkshire Medical Center, and Berkshire Area Health Education Center (AHEC), will be held during July, 1988. Course offerings include "Advances in Cardiology," July 14-16, 1988, and "Special Challenges in General Medicine," July 21-23, 1988. Geared to the Primary Care Physician, these courses will present updates on the latest information critical to the office based management of cardiac problems, and to special problems in primary care. Up to 30 Category I AMA Credits will be offered for attendance at both courses. For more information, call Berkshire AHEC at 413-447-2417.

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WEEKENDS IN PATHOLOGY

The American Society of Clinical Pathologists (ASCP) has announced the locations of the 1988 Weekends of Pathology: June 24-26 at the Hyatt Regency Hotel in Baltimore, Maryland, and July 8-10 at the Le Meridien Hotel in San Francisco, California. Some of the discussions to be presented include: "Tumors of the Ovary and Uterine Corpus," "Neoplastic and Non-Neoplastic Diseases of the Breast" (Baltimore), and "Endoscopic Biopsies of the Small Bowel and Colon," and "Premalignant Breast Diseases and Neoplasms of Low Malignant Potential" (San Francisco). For a free brochure about ASCP Weekends in Pathology, call the ASCP at 800-621-4142.

FIRST INTERNATIONAL SYMPOSIUM ON ORBITAL PLASTIC SURGERY

The Plastic Surgery Educational Foundation will hold its First International Symposium on Orbital Plastic Surgery on June 20-24, 1988, in San Francisco. The faculty is composed of world-wide authorities. More information may be obtained by writing to the Plastic Surgery Educational Foundation, 233 North Michigan Avenue, Suite 1900, Chicago, Illinois, 60601.

THIRD ANNUAL PLASTIC SURGERY OF THE BREAST SYMPOSIUM

The Plastic Surgery Educational Foundation and the American Society for Aesthetic Plastic Surgery will co-sponsor the Third Annual Plastic Surgery of the Breast Symposium in Santa Fe, New Mexico, on September 6-9, 1988. This is an advanced course and it is assumed that all attendees will have a practicing knowledge of plastic surgery of the breast. For more information, write the Plastic Surgery Educational Foundation, 233 North Michigan Avenue, Suite 1900, Chicago, Illinois, 60601.

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You know—perhaps firsthand—how treating a borderline patient can become a vicious circle. The harder you try to help, the more resistant or even abusive your patient becomes, until both of you are left frustrated and exhausted.

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The process is not easy. Serious personality disorders do not lend themselves to a "quick fix." But we are encouraged by the number of our patients who have, in time, broken out of the vicious circle.

If you would like to know more about the Sheppard Pratt approach to the borderline patient and other patients with severe personality disorders, contact the Admissions Office, (301)339-4070, The Sheppard and Enoch Pratt Hospital, 6501 North Charles Street, P.O. Box 6815, Baltimore, MD 21285-6815.

THE PERSONALITY DISORDER TREATMENT PROGRAM

President's Page

ARBITRATION— A RATIONAL ALTERNATIVE?

The search for appropriate tort reform has become antagonistic, costly and has consumed an enormous amount of time of good faith professionals who seek to alleviate what has become an irritating, expensive, and sometimes debilitating experience.

Several months ago, I asked the attorneys representing the Society to suggest a better way to ameliorate these problems. Since then, I have met with them a number of times, and they have provided me with written materials, legal research and concepts, which while not new, have been put together in unique fashion and that I believe will remove many of the worst elements of the present system.

As physicians, our primary objective is the welfare of our patients. From time to time the relationship between physician and patient is threatened, either because of a claim that a physician may feel must be asserted against the patient or because of a claim that the patient feels must be asserted against the physician.

We have never asked for anything more than a fair resolution of such complaints. We believe that our attorneys have suggested just such a system.

Their proposal does not attempt to remove a single, substantive right from physician or patient. They have proposed that *at the inception* of the physician's relationship with the patient, at a time when there is no anger, emotion, or prejudice, that the physician and the patient agree to resolve all future differences by arbitration rather than by court suit.

This system has advantages for both the physician and the patient. First, all substantive rights and defenses currently available remain intact.

Second, the arbitration hearings are generally less time consuming. This is vitally important both to the physician who can ill afford weeks out of the office for preparation and court time; as well to the plaintiff who also can ill afford to miss time from work, family and other important pursuits.

Third, arbitration is faster. The time from filing to decision is generally much less. One reason is that both parties have much more control over scheduling and are not depending on overloaded court dockets.

Fourth, the system is much less expensive. Those with experience in arbitration and court litigation will confirm that the legal expense attendant upon an arbitration hearing is significantly less than the expense attendant upon litigation.

Fifth, and perhaps most important of all, experienced litigators and arbitrators tell us that the arbitration system has been used successfully for decades to resolve important issues without destroying the relationship between the contesting parties.

No matter the claim, no matter what the situation, no physician wants a hostile patient. The feeling of hostility frequently generated in litigation is much less common in arbitration. For example, labor unions and management often arbitrate hotly contested issues. The discharge of an employee for theft, intoxication or other misconduct can produce high emotions, yet a quick and simple hearing before an impartial panel of experienced persons does much to eliminate

continuing strife. Similarly, construction firms have used this device for years to resolve differences involving millions of dollars, and frequently leave opposite sides of an arbitrator's table to return to work as a team.

It is my earnest hope that arbitration will find broad application in the medical community, that physician and patient will approach it in good faith and with good will towards one another, and that differences between physician and patient may be resolved so that each may also leave the arbitrator's table and work together for the benefit of the patient.

The product of the project which I asked our attorney to undertake appears in this publication. Every member of the Society should read it, and offer any suggestion he or she may have.

Martin J. Cosgrove, M.D.

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BRIEF SUMMARY

CONTRAINDICATIONS
There are no known contraindications to the use of sucralfate.

PRECAUTIONS
Duodenal ulcer is a chronic, recurrent disease. While short-term treatment with sucralfate can result in complete healing of the ulcer, a successful course of treatment with sucralfate should not be expected to alter the post-healing frequency or severity of duodenal ulceration.

Drug Interactions: Animal studies have shown that simultaneous administration of CARAFATE (sucralfate) with tetracycline, phenytoin, digoxin, or cimetidine will result in a statistically significant reduction in the bioavailability of these agents. The bioavailability of these agents may be restored simply by separating the administration of these agents from that of CARAFATE by two hours. This interaction appears to be nonsystemic in origin, presumably resulting from these agents being bound by CARAFATE in the gastrointestinal tract. The clinical significance of these animal studies is yet to be defined. However, because of the potential of CARAFATE to alter the absorption of some drugs from the gastrointestinal tract, the separate administration of CARAFATE from that of other agents should be considered when alterations in bioavailability are felt to be critical for concomitantly administered drugs.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Chronic oral toxicity studies of 24 months' duration were conducted in mice and rats at doses up to 1 gm/kg (12 times the human dose). There was no evidence of drug-related tumorigenicity. A reproduction study in rats at doses up to 38 times the human dose did not reveal any indication of fertility impairment. Mutagenicity studies were not conducted.

Pregnancy: Teratogenic effects. Pregnancy Category B. Teratogenicity studies have been performed in mice, rats, and rabbits at doses up to 50 times the human dose and have revealed no evidence of harm to the fetus due to sucralfate. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when sucralfate is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS
Adverse reactions to sucralfate in clinical trials were minor and only rarely led to discontinuation of the drug. In studies involving over 2,500 patients treated with sucralfate, adverse effects were reported in 121 (4.7%).

Constipation was the most frequent complaint (2.2%). Other adverse effects, reported in no more than one of every 350 patients, were diarrhea, nausea, gastric discomfort, indigestion, dry mouth, rash, pruritus, back pain, dizziness, sleepiness, and vertigo.

OVERDOSAGE
There is no experience in humans with overdosage. Acute oral toxicity studies in animals, however, using doses up to 12 gm/kg body weight, could not find a lethal dose. Risks associated with overdosage should, therefore, be minimal.

DOSAGE AND ADMINISTRATION
The recommended adult oral dosage for duodenal ulcer is 1 gm four times a day on an empty stomach.

Antacids may be prescribed as needed for relief of pain but should not be taken within one-half hour before or after sucralfate.

While healing with sucralfate may occur during the first week or two, treatment should be continued for 4 to 8 weeks unless healing has been demonstrated by x-ray or endoscopic examination.

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Issued 1/87

References:

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3. Brandstaetter G, Kratochvil P: *Am J Med* 79 (suppl 2C):36-38, 1985.
4. Marks IN, Wright JP, Gilinsky NH, et al: *J Clin Gastroenterol* 8:419-423, 1986.
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MAY 1988

CARDIAC DOPPLER ECHOCARDIOGRAPHY PRINCIPLES AND APPLICATIONS

Christopher H. Wendel, M.D.

Introduction

For the past decade, M-mode and 2-dimensional echocardiography have proven to be invaluable in the assessment of cardiac anatomy. Many cardiac anomalies have distinct echocardiographic appearances. However, the hemodynamic consequences of these anomalies could only previously be assessed by cardiac catheterization. The application of the Doppler principle to the echocardiographic examination permits a non-invasive assessment of blood flow comparable to the cardiac catheterization technique. Thus, this portion of the cardiac ultrasound examination is complementary to the M-mode and 2-dimensional exam. It is feasible that in certain specific clinical situations, the Doppler echocardiographic examination may be a better alternative than cardiac catheterization. For example, children with congenital valvular aortic stenosis often require serial cardiac catheterizations to determine the pressure gradient across the stenotic lesion. This value is crucial in the timing of valvular surgery. Doppler echocardiography is quite successful in determining the same pressure gradient non-invasively, eliminating the risk and cost of frequent catheterizations. This review will explore the principles of the Doppler exam and discuss its clinical uses in more detail.

Doppler Principles

In 1842, an Austrian physicist, Christian Johan Doppler, described the principle which bears his name: the frequency of a transmitted sound is altered when the source of that sound is moving. A familiar example of this principle at work is the radar speed detection device used by state police. This device emits sound energy in the radar frequency range at a constant rate. The sound waves are reflected by moving automobiles, but attain a higher frequency due to the motion of the vehicle. The radar device analyzes the reflected sound waves to determine the difference between the emitted and the received frequencies. This difference is termed "the Doppler shift frequency" from which the car's velocity can be mathematically determined. The device works on a variation of the Doppler principle, depending upon the property of any moving structure to backscatter energy at a frequency different than the transmitted one.

In vascular applications, the ultrasound energy is the "radar" and the circulating red blood cells are the "automobiles." The red cells reflect ultrasonic energy emitted from the transducer on the chest wall; the difference in the reflected sound energy from the emitted frequency is due to the velocity of the red cells and the direction of interrogation. Maximal velocity detection is best attained when the direction of interrogation is parallel to blood flow. These factors are mathematically related by the equation $V = (Fr-Ft)c / 2ft \cos \Theta$, where V is the blood flow velocity, C represents the velocity of sound in body tissues and is measured at 1560 meters per second, Ft is the transmitted frequency, Fr is the received frequency, and theta (Θ) represents the angle

Dr. Wendel is a cardiologist in private practice in Wilmington, and Elkton, Maryland. He is also director of the Omega Cardiographic Lab in Newark.

between the direction of interrogation and the actual direction of blood flow. Note that (Fr-Ft) actually represents the Doppler shift frequency.

Although both the transmitted and received frequencies are in the megahertz range, the difference between the two is very small and falls within the kilohertz range. Thus, the Doppler shift frequency is audible and easily appreciated by most commercially available Doppler echo machines. It is also important to note the effect of the angle theta (θ). As this angle increases the maximal Doppler shift frequency discernible for a given constant, velocity decreases. This illustrates one of the salient points in Doppler echocardiography: the investigator must make every attempt to attain a direction of interrogation that is parallel to blood flow.

Continuous wave and pulsed Doppler represent the two methods used in cardiac applications of this principle. They are most often used in a complementary fashion.

Continuous wave Doppler employs two separate dedicated piezoelectric elements. One of these elements is dedicated to the continuous transmission of ultrasonic energy. The other is dedicated to the continuous reception of the reflected ultrasonic waves. Since the analysis of the reflected ultrasonic energy is continuous, very high frequency shifts are attainable. However, the reflected frequencies impinging on this piezoelectric element are generated from all points along the line of interrogation. Therefore, it is not possible to determine the exact location of blood flow which generates the highest velocities. Continuous wave Doppler thus allows the measurement of very high blood flow velocities, but at a sacrifice of discerning specific locations.

Pulsed Doppler echocardiography employs a single piezoelectric crystal which transmits and receives ultrasonic energy. In this method, the piezoelectric element emits a brief burst of ultrasonic energy and then remains dormant for a small period of time. At the end of this time interval, the element is again activated, but in a receptive mode. It analyzes reflected ultrasonic energy for only a brief instant in time. Since the speed of sound in the body tissues is constant, the delay between the emission of a given burst and its reception establishes a distance or depth from the transducer. Changes in this time interval determine the depth along the line of interrogation at which velocity profiles are obtained. However, the next burst of ultrasonic energy cannot be emitted until the previous burst has been received and analyzed. Therefore, deeper sample volumes require a longer period of time between emission and reception of the ultrasonic energy. This decreases the ability of the sampling system to measure higher blood flow velocities. Pulsed Doppler echocardiography allows the investigator to specify exact locations within the cardiac chambers to analyze blood flow. However, it is limited in its quantification of high flow velocities. The maximum frequency shift discernible in the pulsed system is equal to one half of the pulse repetition frequency. Frequencies beyond this limit are displayed in an ambiguous fashion and are termed "aliasing." This has been the major deficit of pulsed Doppler echocardiography: as the depth of sample volume increases, the maximal velocity detectable decreases.

One way of circumventing this problem is to combine continuous wave Doppler with pulsed Doppler analysis. For a given line of interrogation, the pulsed system will permit location of the highest velocity jet and a switch to the continuous wave system will permit quantification of the blood flow velocity at this point.

After the returning frequencies are analyzed by the Doppler machine, the output is displayed in both an audible and graphic fashion, which is helpful to the experienced echocardiographer in discerning normal and abnormal flows. The graphic display is much easier to analyze and quantitate. The analyzed Doppler signal is displayed in real time, resulting in a wave form of velocity (vertical axis) and as a function of time (horizontal axis). Velocity toward the transducer is designated in a positive direction and velocity away from the transducer is given a negative direction. From the display of flow across the semilunal valves, the ejection time, and preejection period are easily detected (Fig. 1). Flow across the mitral and tricuspid valve resembles the M-mode echocardiographic appearance of anterior mitral leaflet motion (Fig. 2). Alterations of these flow profiles are the earmark of valvular heart disease.

Stenotic Valvular Heart Disease

To adequately assess valvular stenosis, the velocity data obtained from the ultrasound investigations must be converted to useful information in the form of pressure data. This is accomplished by using the Bernoulli equation, which mathematically relates the pressure drop across a stenotic lesion to the resulting velocity of flow across the stenosis. A simplified version of this equation is employed which neglects the alterations of velocity secondary to blood viscosity and inertial forces. Simply stated, $p = 4V^2$, where p represents the pressure drop, and V represents the velocity range across the stenosis. This simple

FIGURE 1

Doppler velocity profile of normal pulmonic flow. The pulsed Doppler tracing was obtained from the second left intercostal space with the sample volume placed distal to the pulmonic valve. Since flow is directed away from the transducer, it is displayed in a negative direction. The arrows indicate opening and closing pulmonic valve clicks. The time interval between these two clicks represents the ejection time (ET). The preejection period (P) is the interval from the onset of the QRS to the opening valve click. Acceleration time (AT) is measured from the opening valve click to the point of peak systolic flow.

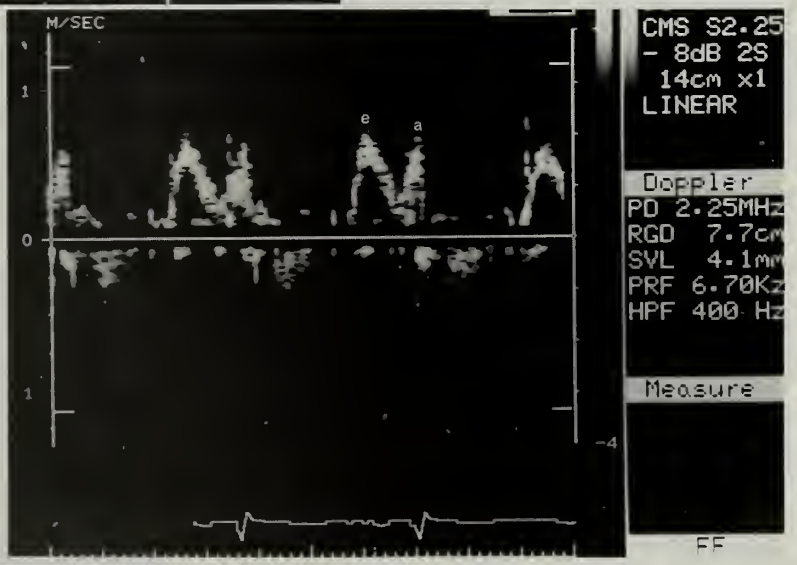

FIGURE 2

Doppler velocity of normal mitral flow. This tracing was obtained from the apical four chamber view with the pulsed Doppler sample volume placed distal to the mitral leaflets in the left ventricular inflow tract. Note how the diastolic velocity profile resembles the M-mode echocardiographic appearance of the anterior mitral leaflet. The peak velocity in early diastole is termed the E-point (e); and in normal individuals it should exceed the peak velocity from atrial contraction or A-point (a). The A-point to E-point ratio should be less than 1.

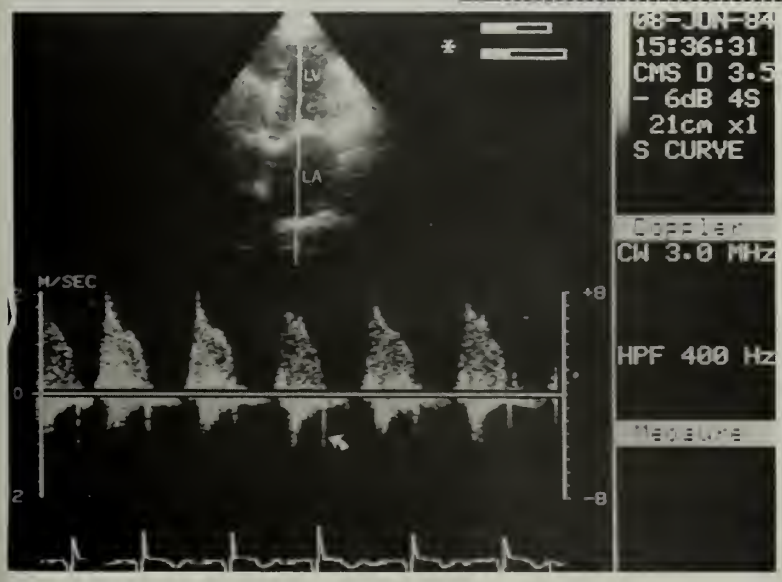

FIGURE 3

Doppler flow profile in mitral stenosis. As illustrated in the upper portion of the photograph, the continuous wave assessment of mitral flow is obtained from the apical four chamber projection with a line of interrogation directed across the mitral valve. The lower portion of the picture displays the mitral velocity profile. Compare this with the normal profile in Figure 2, and note that the velocity is much higher in this patient, indicating a fair degree of stenosis. The arrows indicate the mitral closing sound. Also, mitral flow is more turbulent as indicated by the dispersion of the flow profile.

equation equips the Doppler investigator with the necessary information to characterize valvular stenosis.

Mitral Stenosis

In the Doppler assessment of valvular mitral stenosis, flow profiles are best obtained from the apex. Indeed, in almost all situations, the investigator should be able to orient the line of interrogation parallel to blood flow entering the left ventricle. The resultant wave form is analyzed for both its velocity profile and for an entity termed "pressure half-time." Combination of these entities allows for an excellent assessment of the stenotic mitral valve.[1]

The increased velocity profile of diastolic flow across the mitral valve indicates a relatively high pressure drop between the left atrium and left ventricle (Fig. 3). The peak pressure drop across the mitral valve can be obtained at the E-point of the flow profile by solving for the Bernoulli equation. The mean pressure gradient across this valve is obtained by calculating several pressure values for a single flow profile and averaging the resultant sum. Several studies have indicated an excellent correlation between the Doppler derived pressure data and cardiac catheterization data.[1,2]

It is well known that simple calculation of a pressure gradient across a stenotic mitral valve is inadequate in predicting the degree of stenosis. Such measurements fail to consider the effects of heart rate and cardiac output. Most clinicians prefer an exact calculation of mitral valve area prior to subjecting a patient to surgery. Usually this can be attempted with serial short axis 2-dimensional echo views. However, this technique may prove suboptimal in patients with heavily calcified mitral valves or in those who have already experienced mitral commissurotomy. In this situation, the assessment of mitral pressure half-time provides objective data on the severity of the mitral valvular disease.[1]

Pressure half-time was first described by Libanoff and Robard in 1966 to better assess mitral stenosis in patients with concomitant mitral regurgitation.[3] The pressure half-time is the amount of time required for the instantaneous diastolic pressure drop to fall to one half of its peak value. Hatle applied this concept to the Doppler flow characteristics across the mitral valve in patients who had mitral regurgitation alone, combined mitral stenosis and mitral regurgitation, and normal controls.[1] In normal patients the mitral half-time varied between 20 and 60 ms (mean = 46 ms). In patients with mitral regurgitation alone, the half-time fell between 35 and 80 ms (mean = 50 ms). However, patients with mitral stenosis, whether alone or in combination with mitral regurgitation, displayed half-times above the normal range and between 90 and 383 ms. In addition, patients with severe mitral stenosis (that is, a mitral valve area less than 1.0 cm^2) displayed excessively prolonged half-times between 233 and 383 ms. It is interesting to note that the patients with severe mitral stenosis exhibited pressure drops as low as 5 mm Hg and as high as 30 mm Hg. Hatle's group also derived a simple equation which allowed estimation of mitral valve area based on half-time alone: MVA = 220 / $T_{1/2}$, where MVA is the mitral valve area and $T_{1/2}$ is the mitral valve half-time (Fig. 4). Stamm and Martin applied this formula to a series of patients with mitral stenosis and demonstrated an excellent correlation of 0.87 with cardiac catheterization derived mitral valve area.[2] Thus, this technique appears to be of great value in the assessment of mitral stenosis.

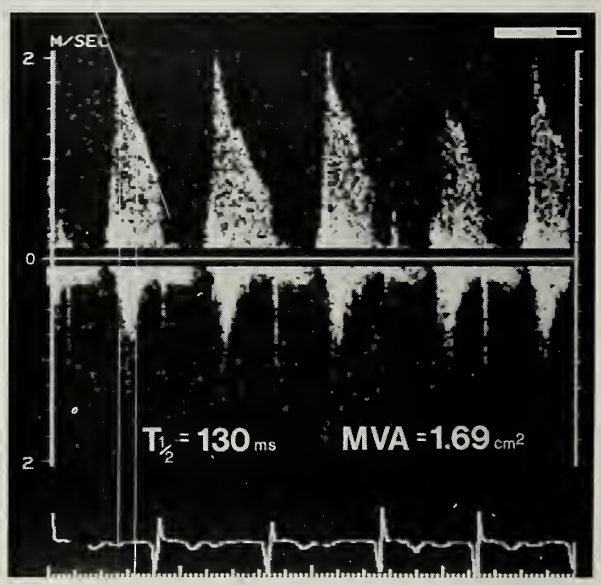

FIGURE 4

Calculation of mitral valve area (MVA) from the pressure half-time measurement ($T_{1/2}$). The slope of the maximum velocity curve is a function of the degree of obstruction; such that severe obstruction produces slow decreases in the velocity and mild obstruction yields a more rapid descent. This time course can be expressed as the "pressure half-time," or the time required for the mitral pressure gradient to fall to one-half of its initial value ($T_{1/2}$). This value correlates well with mitral valve area (MVA) by the formula: MVA(cm^2 = 220 / $T_{1/2}$). Normal individuals demonstrate half-times less than 60 ms and patients with mitral stenosis display half-times between 100 and 400 ms. Those with values exceeding 200 ms usually have an effective valve area less than 1.0cm^2.

A combination of the pressure drop and mitral pressure half-time in patients suffering from mitral stenosis should be obtained by Doppler echocardiography (Table 1). In normal patients the pressure drop is obviously low and the half-time is short. In patients with severe mitral stenosis and normal cardiac output, the pressure gradient is usually high and the mitral half-time excessively prolonged. But when the pressure drop is low and the mitral half-time is still prolonged, the patient may have severe mitral stenosis and a depressed cardiac output. Increased flow states, seen in patients with mitral stenosis and concomitant mitral regurgitation, are characterized by a high pressure gradient and a short pressure half-time. Thus, when mitral insufficiency is hemodynamically significant, the pressure half-time will indicate whether obstruction or regurgitation is the predominant lesion. The assessment of the severity of mitral stenosis is best determined by Doppler echocardiography rather than by cardiac catheterization.

Tricuspid Stenosis

Tricuspid stenosis is relatively uncommon, as indicated by the paucity of clinical studies investigating it. Doppler assessment of tricuspid blood flow is best obtained from the apical 4 chamber view. The flow profiles appear similar to those obtained in patients with mitral stenosis, and tricuspid valve half-times are also elongated. The principles described in the assessment of mitral stenosis should also apply in this rare clinical situation.

TABLE 1

PRESSURE GRADIENT	MITRAL HALF-TIME	DISEASE STATE
low	short	Normal
high	prolonged	Mitral Stenosis with normal cardiac output
low	prolonged	Mitral Stenosis with depressed cardiac output
high	short	High flow state as in combined MS/MR with insufficiency predominant

A comparison of the pressure gradient across the mitral valve with the pressure half-time yields important implications concerning the severity of mitral valve disease.

Aortic Stenosis

The echocardiographic visualization of aortic stenosis has been of little value in determining the severity of this disease. Clinicians have relied upon the catheterization-derived aortic gradient and aortic valve area to determine the severity of this lesion as a prerequisite for valve replacement. Doppler echocardiography permits a non-invasive assessment of the pressure gradient across the aortic valve and may also prove successful in calculating valve area.

As stated previously in this report, it is imperative that the echocardiographer place the line of Doppler interrogation parallel to blood flow. In no other instance is this more critical and difficult to perform than in the assessment of aortic valvular stenosis. Obtaining the peak flow profile should be attempted from multiple views including the apical, suprasternal, right supraclavicular, and high right parasternal views. In each of these projections it may be necessary to position the patient in either the right or left lateral decubitus, or supine. Due to the high flow velocities across the stenotic lesion, continuous wave Doppler must be used (Fig. 5). When these efforts are fruitful, the Doppler-derived aortic valve gradient may demonstrate an excellent correlation with cardiac catheterization data. Stamm and Martin studied 31 elderly patients with aortic stenosis.[2] In 26 of these patients, adequate Doppler studies were obtained and revealed a correlation of 0.94 with cardiac catheterization-derived gradients. In no instance was there significant overestimation of the aortic gradient.

It is well known that patients with long-standing severe aortic stenosis may demonstrate left ventricular dysfunction. In that case, cardiac output is depressed and the resultant gradient across the stenotic valve will drop. Thus, the determination of the severity of aortic valvular stenosis is better served by an actual calculation of aortic valve area. This calculation requires the determination of cardiac output which is readily obtained by catheterization. Recently, several investigators have determined cardiac output with Doppler echocardiography.[4,5,6] Sahn and Valdez-Cruz have used this method and derived a modified Gorlin equation to calculate valve area in patients with both aortic and pulmonic stenosis.[7] Although only a small number of patients were examined, the data appear quite promising for the non-invasive determination of aortic valve area. Obviously, other studies are required to verify the validity of this technique.

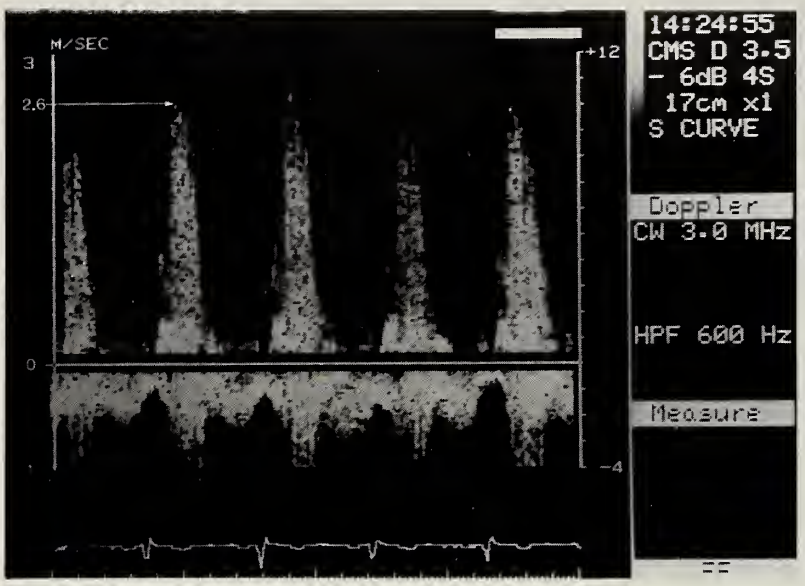

FIGURE 5
Continuous wave Doppler flow profile in a patient with aortic stenosis. The highest velocity attained is 2.6 m/sec, which corresponds to a pressure gradient of 27 mm Hg between the left ventricle and aorta.

Pulmonic Stenosis

Pulmonic stenosis is commonly encountered in children. Access to pulmonic flow profiles is best achieved from the high left parasternal window. Although blood flow is directed away from the transducer, it is easy to position the line of interrogation parallel to this flow. Thus, calculation of gradients across the stenotic pulmonic valve is easy to obtain. Lima, et al, examined 16 patients with pulmonic stenosis and demonstrated a correlation of 0.98 with catheterization-derived gradients.[8] Kosturakis, et al, confirmed this high correlation and accurately derived the pulmonic valve area using Doppler-derived cardiac output and the modified Gorlin equation described above.[7] Preliminary results from such clinical trials in children with valvular pulmonic stenosis indicate that the Doppler echocardiographic method is quite useful in the follow-up care of these patients.

Regurgitant Valvular Heart Disease

Traditional M-mode and 2-dimensional echocardiography have only provided indirect evidence of regurgitant valvular lesions. Chamber dilatation, wall hypertropy, and valvular flutter help in determining the presence of regurgitant lesions, but are unable to adequately quantify their severity. Doppler echocardiography can accurately detect these lesions by the so-called mapping technique. In addition, there have been several efforts to quantify and calculate regurgitant volumes. Better detail of these techniques is provided below.

Mitral Regurgitation

The best view for the assessment of mitral regurgitation is the apical 4 chamber in which the pulsed Doppler sample volume is placed in the left atrium. However, mitral regurgitation can also be detected from the long axis parasternal approach. This is due to the radial component of the velocity profile and the turbulence created by a regurgitant jet. It is not unusual to find patients in which mitral regurgitation can only be found on the long axis parasternal approach as opposed to the apical view. Most studies indicate that the sensitivity in detecting mitral regurgitation by Doppler echo is 94% with a specificity of 89%.[9] Extremely high velocities are seen in the condition due to the wide difference in pressures between the left ventricle and atrium during systole.

The easiest approach in determining the severity of mitral regurgitation is through the flow mapping technique. With this method, the echocardiographer slowly traverses the entire left atrium in an attempt at tracing the regurgitative jet. In patients with 1+ mitral regurgitation the turbulent regurgitation flow can only be appreciated just proximal to the mitral leaflets. In contrast, patients with 4+ mitral regurgitation will demonstrate the regurgitant jet to the posterior wall of the left atrium. This method is fast and easy to accomplish.

A semi-quantitative method for the assessment of mitral regurgitation was described by Nichol, et al.[10] Assuming that the aortic valve is normal, the investigator attempts to record maximal systolic aortic blood flow. Systole is then divided in half and the area under each half of the aortic flow velocity is compared. In normal patients, this ratio

is approximately 1:1, but in patients with hemodynamically significant mitral regurgitation, 53-79% of the total area was found within the first half of the aortic flow velocity profile. Nichol reports a strong correlation with cardiac catheterization and states that this method is much better than the subjective grading of regurgitation which is prevalent with cardiac catheterization.

Tricuspid Regurgitation

Once again, pulsed Doppler echo is best utilized in the assessment of tricuspid regurgitation. Optimal views are the apical 4 chamber and the parasternal long axis view. Most centers use the mapping technique to grade the severity of the tricuspid regurgitation. Some investigators have attempted quantification by assessing antegrade and retrograde blood flow within the hepatic vein. This method is time-consuming and offers little additional information to the surgeon prior to valvular heart surgery.

Aortic Regurgitation

As in mitral regurgitation the best view for the assessment of aortic regurgitation is the apical 4 chamber view in which the pulsed Doppler sample volume is placed in the left ventricular outflow tract. However, the long axis parasternal view will also yield this information. Combining the pulsed Doppler recording with 2-dimensional echo allows adequate placement of the sample volume within the left ventricular outflow tract. The sensitivity of pulsed Doppler echocardiography in the detection of aortic regurgitation is 97% with a specificity of 95%.[11]

The mapping technique can also be applied to aortic regurgitation. If aortic insufficiency is detected immediately below the aortic valvular leaflets it can be termed "1+." Aortic insufficiency reaching 2+ requires tracing the regurgitant volume to the tips of the anterior mitral leaflets. The level of 3+ can be traced to the level of the papillary muscles, and 4+ aortic insufficiency occurs when the regurgitant jet is found in the apex of the left ventricle. This technique correlates well with the subjective cardiac catheterization determination of aortic regurgitation.[11]

A semi-quantitative method for the determination of the severity of aortic insufficiency involves the assessment of descending aortic blood flow from the suprasternal notch.[12] Due to the position of the transducer, normal systolic blood flow travels away from the transducer, yielding a negative pulse tracing on the Doppler display. But in early diastole, a positive flow profile detected in the descending aorta is an abnormal finding that represents regurgitation across the aortic valve. A comparison of the relative areas under both the diastolic and systolic velocity curves in this setting are an indication of the severity of the regurgitant lesion.

Pulmonic Regurgitation

All pulmonic flow profiles are best obtained from the left parasternal view in the second or third intercostal space. The detection of pulmonic regurgitation appreciated from this window is sensitive. The pulsed Doppler sample volume is placed in the right ventricular outflow tract and analysis of diastolic blood flow is noted. Due to the relative benign nature of pulmonic regurgitation, little attempt is made to quantify or map its severity.

Multivalvular Disease

This report has reviewed the application of the Doppler technique to single valvular disease. However, it is not uncommon for the clinician to encounter patients with multiple valve disease. This scenario usually occurs when a patient presents with a history and physical examination, EKG, chest x-ray, and even an M-mode/2-dimensional echocardiogram, which provide ambiguous information as to the exact valvular disease precipitating the patient's symptoms. Both pulsed and continuous wave Doppler are valuable in detecting the separate lesions in combined valvular disease.

To illustrate this point, Saal and Pearlman evaluated 45 patients with rheumatic mitral stenosis to search for associated aortic regurgitation.[13] All results were compared to a clinical examination and were confirmed by aortography. Doppler echocardiography demonstrated a 97% sensitivity in detecting associated aortic regurgitation. The clinical cardiologist was only 79% sensitive. This illustrates the effectiveness of Doppler echocardiography in the assessment of multivalvular heart disease.

Prosthetic Valves

This report would be remiss if it did not include a discussion of Doppler echocardiography in the assessment of prosthetic valves. All physicians are aware of the shortcomings that M-mode and 2-dimensional echocardiography possess in the assessment of patients with valvular prostheses. Due to the echogenicity of prosthetic valves, malfunction of these prostheses is difficult to discern. Doppler echocardiography appears to bridge this gap quite adequately.

One of the most common problems with abnormal prosthetic valves is the incidence of regurgitation. Pearlman observed 20 patients with aortic valve prostheses and 30 patients with mitral

valve prostheses to compare clinical and Doppler assessment of prosthetic regurgitation.[14] Doppler proved 91% sensitive compared to 73% sensitivity of the clinical examination of patients with aortic prosthetic regurgitation. In patients with mitral prostheses, the Doppler examination was 86% sensitive compared to the clinical sensitivity of 71%. In each instance placement of the pulsed Doppler sample volume behind the valve in question was easily achieved.

Another problem with valvular prostheses involved stenosis either secondary to thrombus formation or recurrent fibrocalcific degeneration. As in native valve stenosis, Doppler-derived pressure gradients can be determined from the Bernoulli equation. However, since prosthetic valves are not perfect replacements of native valves, an inherent gradient across the prosthesis exists and must be accounted for in assessing the significance of gradients detected in disease states. Thus, base-line post-surgical Doppler echocardiographic examinations of patients with valve replacement is mandated.

Other Applications of Doppler Ultrasound

Although the major thrust of Doppler echocardiography has been the assessment of valvular heart disease, other uses of this technique have been found. These will be discussed briefly.

Determination of Cardiac Output and Shunt Flow Ratios

The value of knowing cardiac output in clinical medicine is readily apparent. Until recently, this value was only obtainable by invasive methods. However, advances in Doppler ultrasound now permit a non-invasive calculation of cardiac output, which appears to correlate quite well with values derived by the thermodilution technique.[4] In this situation, Doppler echocardiography is used to calculate stroke volume by the equation: SV = CSA x V x ET, where SV is the stroke volume, CSA represents the cross-sectional area, V is the velocity, and ET is the ejection time. Although this equation appears simple, its practical application requires a great deal of time and care. Accurate determination of cross-sectional area by 2D echocardiography is a painstakingly slow process. In addition, the peak flow velocity must be diligently searched. Although multiple determinations are required for each patient, the effort is worthwhile and can be accurate.

Another method for analyzing cardiac output evaluates blood flow across the mitral anulus. The difficulty with this method arises from the variability in mitral anulus size during diastole. Valdez-Cruz has developed a formula which determines the average mitral anulus in diastole.[6] This value is used as the cross-sectional area and is multiplied by the average velocity and ejection time for the determination of stroke volume. In her experienced hands, Dr. Valdez-Cruz has demonstrated a correlation of 0.94 with cardiac output determined by thermodilution techniques. Similar investigational studies are being applied to tricuspid valve flow to calculate the cardiac output across this valve anulus.

In many instances, the valvular anulus used for the determination of cardiac output will be a function of which valve is visualized best. However, in patients with intracardiac communications, the orifice selected is important because blood flow will vary depending on the type of lesion which is present. The relative flow ratios in the pulmonic and systematic circulation (Qp::Qs ratio) can be calculated with this technique. Preliminary work of this type on patients with atrial septal defects was reported in 1983 by Sanders, et al,[15] and demonstrated a correlation with catheterization-derived Qp/Qs ratios of 0.85. Thus, the future holds great promise for this technique.

Dilated Cardiomyopathy

Gardin, et al, used Doppler echocardiography to assess patients with dilated cardiomyopathy.[16] In these patients the aortic peak flow velocity was dramatically reduced as was the mean velocity. In normal patients the peak flow velocity averages 95 cm/sec. But in the patients with dilated cardiomyopathy the average peak flow velocity was nearly halved to 47 cm/sec. Additional findings in these patients included a decrease in the aortic ejection time and a decrease in the average aortic acceleration. In those patients who remained in sinus rhythm the A:E ratio of the mitral inflow pattern was greater than one, reflecting a significant decrease in left ventricular compliance.

As a corollary to the Doppler flow profiles obtained in cardiomyopathy, Elkayam, et al, evaluated the effects of vasodilitory therapy in congestive heart failure.[17] In these patients, changes in Doppler aortic flow profiles were correlated with changes in stroke volume and systemic vascular resistance. Those patients who demonstrated a beneficial effect of acute vasodilitory intervention showed dramatic increases in peak aortic flow. This method should prove useful in assessing the response to vasodilatory therapy in all patients with congestive heart failure.

Hypertrophic Cardiomyopathy

In patients with hypertrophic cardiomyopathy adequate assessment of ascending aortic blood

flow is necessary. In those patients who do not demonstrate obstruction with systole the aortic flow contour appears normal. But when obstruction occurs, a spike and plateau pattern is noted in the flow profile. The mean ejection time is also prolonged. However, the peak flow velocity in hypertrophic cardiomyopathy with or without obstruction will always be the same.

Pulsed Doppler echocardiography is also valuable in patients with hypertrophic cardiomyopathy to search for mitral regurgitation, which is commonly seen in patients who demonstrate obstruction. A small study of 11 patients with hypertrophic cardiomyopathy demonstrated mitral regurgitation in four of five patients with hypertrophic obstructive cardiomyopathy. In each instance, the onset of regurgitation occurred with the onset of systolic anterior motion on the M-mode echocardiogram.

Determination of Pulmonary Artery Pressure

Several clinical situations arise in which the assessment of pulmonary artery pressure is necessary. For example, in patients with mitral stenosis, it is valuable to know whether pulmonary hypertension exists. Since pulmonary profiles are relatively easy to obtain, analysis of profile characteristics have provided clues to the presence of pulmonary hypertension. Jiang, et al, evaluated patients for pulmonary hypertension and developed a simple formula: mean PAP = (26 x PEP/AT) - 4, where the mean pulmonary artery pressure is a function of the pre-ejection period (PEP) and acceleration time (AT).[18] His data demonstrated a correlation of 0.86 with cardiac catheterization-derived pulmonary pressures. He also noted that all patients with pulmonary hypertension had an acceleration to ventricular ejection time ratio less than 0.33. Further studies are needed to verify the findings he described.

Conclusion

This report has attempted to illustrate the usefulness of Doppler echocardiography. Although its major role appears to be in the assessment of valvular heart disease, other hemodynamic parameters can be obtained from an accurate Doppler exam. It is a technique which is complementary to M-mode and 2-dimensional echocardiography; it requires considerable skill and patience by the investigator. Adequate performance of this portion of an echocardiographic examination will require at least twice as much time to perform as the normal M-mode 2-dimensional exam.

Many clinical applications of this technique are being investigated. One dramatic advance is the use of color in Doppler flow mapping. With this technique, Doppler profiles are assigned a color, and this image is superimposed on the 2-dimensional echocardiographic image. This gives the impression of actually watching blood flow into and out of the various cardiac chambers. This allows the visualization of small jets and helps to localize areas requiring more extensive interrogation with continuous wave and pulsed Doppler echocardiography. Also, regurgitant lesions are accurately outlined with the color technique. The most important application of color flow mapping is in the pediatric population, where small ventricular and atrial septal defects are visualized non-invasively. Although further experience with this technique is necessary, it certainly appears that color flow mapping will be the next major advancement in Doppler echocardiography.

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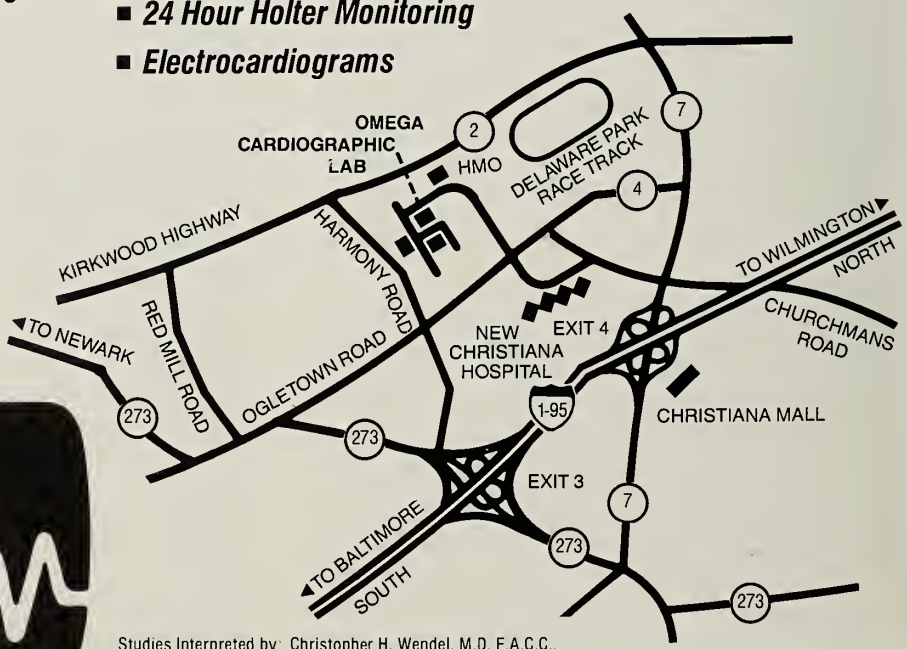

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Special Report

DOCTOR-PATIENT ARBITRATION: A PROPOSAL WHOSE TIME HAS COME

Francis S. Babiarz
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Victor F. Battaglia
Jeffrey S. Marlin
Wayne A. Marvel
Roger Sanders
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Wouldn't it be a blessing if civil jury trials could be completed in one or two days; if cases would not sit on a court docket awaiting trial for over four years; if the anxiety that burdens litigants on both sides could be dissipated within six months; if lengthy and expensive trial practices could be avoided; if protracted and expensive appeals could be avoided? Those benefits and more can be achieved, not within the court system, but by a simple, time-tested and reliable procedure.

Arbitration has long been used to resolve important disputes outside the court system. A common use is the resolution of labor disputes. Almost every collective bargaining agreement contains a requirement for arbitration. This has occurred because labor-management relations is a contentious area. When major disputes of the most sensitive nature are resolved over the arbitration table, labor and management typically leave that table and then return to work as a team. Could it be that arbitration reduces the feelings of resentment and the bitterness that sometimes occurs between litigants? What labor management team could work side-by-side while waiting over five years for a court to solve a dispute?

Contractors and subcontractors use arbitration to resolve major differences because it provides a quick resolution that allows the parties to continue to work together for mutual benefit.

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In fact, if you have a dispute with your stock broker, you will learn that you must *arbitrate* rather than litigate.

The time has come for physician and patient to find a better way to resolve their disputes, and arbitration is that way.

Although arbitration of medical disputes has a long history in other jurisdictions,[1] this device is not common in Delaware, even though it offers distinct advantages for the resolution of disputes between doctors and patients.

A study conducted in California in the 1970s, for example, indicates that arbitration produced fewer claims, faster resolution of claims and lower processing costs than a comparable group that relied on the court system.[2]

One reason for arbitration's infrequent use may be a general lack of familiarity. This article hopes to correct that deficiency.

At heart, arbitration is a substitute for a court trial. It is based on a contract in which the parties agree that disputes will be resolved by an impartial tribunal consisting of one or more persons the parties themselves have mutually selected or accepted. The contract can govern not only disputes already in existence, but also future disputes as well.

In a court trial, the rules of the court and particular statutes govern the procedure to be used. In addition, the court sets the schedule for the case, and this, in turn, is determined by the court's case load. For example, in New Castle County alone, more than 5,500 civil and criminal cases were pending in the Superior Court on June 30, 1987, and the average time for disposition of a civil case after the filing of a complaint was 1,227 days in 1987.[3] Thus, the parties can decide that a case is ready for trial, but then they must endure a long wait because of court backlog.

On the other hand, because arbitration is a creature of contract, the parties themselves specify the pre-hearing procedure and schedule either by specifying those items in the contract or by referring to other rules in existence, such as those of the American Arbitration Association.

For the same reason, they can also control the qualifications of the decision makers. This last factor is one of the more significant advantages over court litigation. In a case involving highly technical issues, a decision maker with expertise can be selected.

Moreover, the forum itself is private between the parties, so that the results are not automatically publicized. Furthermore, the decision of the arbitrators is final so that no lengthy appeal leaves the parties in doubt as to the final outcome long after the "trial" itself has concluded.

Because of these advantages, numerous states have enacted statutes that specifically authorize arbitration agreements in general. In Delaware the statute is 10 *Del.C.* Ch. 57. It governs all arbitration, and is not limited specifically to medical disputes. 10 *Del.C.* Section 5701 states:

> A written agreement to submit to arbitration any controversy existing at or arising after the effective date of the agreement is valid, enforceable and irrevocable, save upon such grounds as exist at law or in equity for the revocation of any contract, without regard to the justifiable character of the controversy, and confers jurisdiction on the Chancery Court of the State to enforce it and to enter judgment on an award.

The statute specifies certain minimum procedures for the hearing, and contains various provisions concerning the relationship between the judicial system and the arbitration process.

In accord with the statutory policy, Delaware has consistently favored arbitration. For example, *Pettinaro Construction Company v. Harry C. Partridge*, 408 A.2d 957 (Del. Ch. 1979), ruled that the public policy of this state is to enforce arbitration agreements. This case further stated that the Delaware statute reflected a policy designed to discourage court litigation, to permit parties to resolve their disputes in a specialized forum that is more likely conversant with their needs, and to provide for the speedy resolution of disputes. In *Falcon Steel Company v. Weber Engineering*, 517 A.2d 281 (Del. Ch. 1986), the Delaware Court of Chancery also held that any doubts concerning the scope of arbitrable issues are to be resolved in favor of arbitration, and that a court can go no further than determining only that a claim is arbitrable.

As a result, although there are no reported Delaware decisions involving the arbitration of medical disputes, the state's public policy strongly favors this process. See also *Farm Family Mutual Insurance Company v. Blevins*, 572 F.Supp. 397 (D.Del 1983).

Other jurisdictions, however, have upheld arbitration agreements in the medical context. In *Doyle v. Giuliucci*, 33 Cal.Rptr. 697 (Cal. Supr. 1965), the California Supreme Court upheld an arbitration decision that was based on an arbitration provision in a contract for medical services between a medical group and the father of a minor. When the plaintiff lost an arbitration hearing, the court was petitioned to vacate that decision. The court held:

> "The arbitration provision in such contracts is a reasonable restriction, for it does not more than specify a forum for the settlement of disputes." *Id.* at 699. See also *Zupan v. Firestone*, 457 N.Y.S.2d 43 (N.Y. App. 1982).

Likewise, in *Guadano v. Long Island Plastic Surgical Group P.C.*, 607 F.Supp. 136 (E.D.N.Y. 1982), a patient signed an arbitration agreement during a preoperative visit. When the plaintiff filed a malpractice suit, the defendant moved to dismiss the case and compel arbitration. The court held that the arbitration provision had been properly explained to the patient and was not unconscionable. It therefore stayed the action and ordered arbitration.

Significantly, none of these cases upheld the arbitration proceeding on the basis of any special statute relating to arbitration in a medical context.[4] Rather, all were based on the general law and public policy of the state.

In this regard, the appendix to this article contains a form that has been carefully drafted to meet the particular requirements of the doctor-patient relationship.

The form is designed as a separate agreement between the doctor and patient governing arbitration alone. It governs not only potential malpractice actions by the patient, but also fee claims by the doctor.

Most importantly, the agreement explicitly reserves to the parties all substantive rights.

In fact, the time for filing a claim *is not* shortened, but rather coincides with the statute of limitations provided by law for that claim. Furthermore, each side is put on exactly the same procedural footing. The agreement also gives the arbitrators authority to resolve pre-hearing disputes so that if one party feels particularly strong about an issue to which agreement is not possible, the arbitrators can resolve that dispute too.

In addition, the title of the contract uses the word "arbitration"; each page of the contract is to be signed by the patient; and immediately above the patient's final signature is a bold face advisory that the contract governs important legal rights and is signed knowingly and voluntarily. The agreement is to be signed in duplicate with the patient retaining a copy.

Although the contract itself does not state this specifically, it is intended to be given to the patient at the inception of the doctor-patient relationship. For this reason, it should be part of the forms every patient signs while waiting for the initial examination. This provides an opportunity for the patient to review the language carefully.

Obviously, an emergency situation would not present that opportunity, and priority treatment should be given whenever necessary without concern for the agreement. The agreement could then be signed at the first opportunity when the patient is not in physical distress that could distract attention from the provisions of the agreement.

This agreement thus provides a way of resolving doctor-patient disputes quickly and inexpensively while retaining all substantive rights of both the doctor and the patient. Before implementing any such contract, however, a doctor should receive approval from his insurance carrier.

The contract cannot be used in every situation, but where available, it presents an opportunity of distinct benefit to both doctor and patient.

Summary

We realize that busy people often do not read their mail. Because of the importance of this matter, the following outline summary is provided for convenience:

I. Introduction
  A. Current problems with the court system
  B. Use of arbitration in other areas
  C. Empirical study of benefits
II. The arbitration process in general
  A. Definition
  B. Comparison between arbitration and court litigation
    1. Court litigation
      a. Rigidity of procedure scheduling
      b. Backlog
    2. Arbitration
      a. Flexibility of procedure
      b. Expertise of arbitrators
      c. Privacy
      d. Finality
III. Legal framework
  A. Delaware arbitration statute
  B. Delaware case law
  C. Case law from other states regarding medical arbitration
IV. Highlights of form agreement
  A. Separate agreement governing all disputes
  B. All substantive rights preserved
  C. Pre-hearing disputes resolved by arbitrator
  D. Miscellaneous items
  E. Signing
    1. Normal
    2. Emergencies
V. Conclusion

References

1. The Ross-Loos Medical Group in California has used arbitration since well before the 1960s. See, *infra*, *Doyle v. Giuliucci*, and Heintz, footnote 2.
2. Heintz. Medical malpractice arbitration: a viable alternative. Arbitration Journal. Vol 34, No 4, 15-18.
3. January 15, 1988 draft report to the 134th General Assembly.
4. Currently, at least 12 states have enacted such laws.

Appendix 1
AGREEMENT TO RESOLVE ALL CLAIMS AND DISPUTES BY ARBITRATION

_____ (Print Name Here) (hereafter "patient") and _____ M.D. on his own behalf and as agent for _____P.A. (hereafter collectively "doctor") hereby agree to resolve by final and binding arbitration all claims and disputes in any way arising out of the doctor's medical treatment or diagnosis of the patient, including all disputes involving the doctor's fees and all claims alleging malpractice on the part of the doctor.

A person shall initiate arbitration by sending the other party to the claim or dispute a written demand for arbitration that identifies the issues to be arbitrated. A person must send the demand for arbitration within the time specified by the applicable statute of limitations governing the claim or dispute.

Within 30 days after the demand is sent, each party shall appoint an arbitrator and give notice of that appointment to the other party. Within 30 days after the second arbitrator has been appointed, the two arbitrators shall select a neutral arbitrator and give notice of their selection to the

parties. If a neutral arbitrator cannot be selected within that time period, the person initiating the arbitration shall apply to the Court of Chancery of the State of Delaware for an appointment of the neutral arbitrator pursuant to 10 *Del.C.* Section 5704.

Not less than 60 days nor more than 180 days from the appointment of a neutral arbitrator, a hearing shall be held on the claim or dispute on a date set by agreement of the parties. At least 50 days prior to the hearing, the parties shall exchange a list of witnesses and other evidence that each party will present at the hearing. Each party consents to the other party examining all documents and records not subject to a privilege relating to the issues to be arbitrated, and if a party's physical or mental condition is in issue that party also consents to a medical examination by a physician selected by the other party.

At the hearing, the arbitrators shall consider all relevant evidence not subject to a privilege that possesses probative value commonly accepted by reasonably prudent persons in the conduct of their affairs. Upon the request of either party, the arbitrators shall decide by a majority vote any procedural issue relating to the hearing. The parties may assert at the hearing any claim or defense available to them in a court of law. The hearing shall not be open to the public.

Within 30 days after the conclusion of the hearing, the arbitrators shall decide the claim or dispute by a majority vote. The decision of the arbitrators shall be final and binding.

The time periods specified in this agreement may be changed at any time by mutual agreement of the parties. This agreement and all resulting arbitration decisions may be specifically enforced and shall be governed by the laws of the State of Delaware, including the Delaware Uniform Arbitration Act, 10 *Del.C.* Chapter 57 and 18 *Del.C.* Ch. 68 except Sections 6802 through 6814.

This agreement and all resulting arbitration decisions shall be binding upon the patient, the doctor and all persons related to them with a claim or dispute described in this agreement, including spouses, children (whether born or unborn), personal representatives, estates, heirs, successors and assigns. As used in this agreement, "person" includes individuals, partnerships, corporations, proprietorships and professional associations. If any term, provision or application of this agreement shall be invalid or unenforceable, all remaining terms, provisions and applications shall not be affected, but shall remain valid and enforceable.

This agreement shall continue in effect until the patient delivers a written revocation to the doctor. This agreement shall continue to apply, however, to all claims and disputes described in this agreement related to any event occurring prior to the revocation.

By signing this agreement, the patient and the doctor specifically recognize and agree that they each waive all their rights to have a court decide all claims and disputes in any way arising out of the doctor's medical treatment or diagnosis of the patient, including all disputes involving the doctor's fees and all claims alleging malpractice on the part of the doctor, and further that no person bound by this agreement shall have any right to a trial by jury with respect to the claims and disputes governed by this agreement.

THIS AGREEMENT GOVERNS IMPORTANT LEGAL RIGHTS. BOTH PATIENT AND DOCTOR AGREE THAT THEY FULLY UNDERSTAND THE TERMS CONTAINED IN THIS AGREEMENT AND VOLUNTARILY AGREE TO BE BOUND BY THOSE TERMS. THIS AGREEMENT IS EXECUTED IN DUPLICATE WITH PATIENT AND DOCTOR EACH RETAINING A COPY.

_____ _____ _____ *(Seal)*
Witness Date Patient

_____ _____ _____ *(Seal)*
Witness Date Doctor
(Name of Professional Association)

_____ _____ *By:*_____ *(Seal)*
Witness Date Doctor

THORACIC OUTLET SYNDROME: A THERAPEUTIC APPROACH BASED ON 115 CONSECUTIVE CASES

Allen L. Davies, M.D.
William Messerschmidt, M.D.

Introduction

In 1982, the senior author reported in this Journal, his personal experience with 47 patients diagnosed as having thoracic outlet syndrome (TOS), and treated by transaxillary resection of the first rib.[1] This series has now grown to 115 patients who have had 122 transaxillary first rib resections with a follow-up period of from six months to 14 years. This expanded experience has led us to solidify our opinions on certain points and to question and modify some of our original positions pertaining to diagnosis and treatment. The following article will delineate our current stance as far as diagnosis, selection of patients for surgery, operative technique, and post operative rehabilitation are concerned. The question of bilateral involvement, acute occlusion of the subclavian vein, and causalgia will be discussed. In these days of DRGs, hospital stay and time lost from work will be reported.

Materials and Methods: Symptoms and Signs

The record of all patients operated on by the senior author since 1972 at The Medical Center of Delaware, St. Francis Hospital, and Alfred I. du Pont Institute were reviewed. Follow-up information was obtained by office visit or telephone interview. In the 115 patients, 122 first rib resections were performed. Seven patients had bilateral resections. Pertinent historical data is shown in Table 1. There were 53 men and 62 women. The average age of the men was 35 years (18-64), and the women 39 years (18-63).

Seventy-five patients had a history of trauma. Auto accidents accounted for 45, 25 were job-related, and five were due to other accidental injuries, including two injuries due to falls in the surf at the Jersey shore.

Previous unsuccessful surgery was not uncommon: 25 patients in our series had 33 prior operations and were either not helped or their symptoms exacerbated.

Presenting signs and symptoms are displayed in Table 2. All patients had neck, shoulder, head, or arm pain which was generally reproducible by changes in the arm position. Numbness and paresthesia was the next most common symptom, seen in 99 patients. Headache was not uncommon, being seen in 30 patients, and was either completely relieved or markedly decreased in 28 patients after surgery.

This particular finding surprised us greatly, and we were careful to point out to the patient that headache would in all probability not be helped by first rib resection. This finding may be explained by relief of trapezius muscle and shoulder girdle muscle spasm, which contributed to the tension-type headache.

The most common physical finding was obliteration or marked decrease of the radial pulse with various maneuvers of the upper extremity, especially of the classical Adson sign. The loss of pulse was often present after only 90% abduction of the involved extremity in many of the more severe cases.

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TABLE 1

HISTORICAL DATA

Patients	No. of patients
Male	53
Female	62
	115
History	
Auto	45
Work Related	25
Other	5
Trauma Documented	75
Previous Surgery	
Scalenotomy	14
Cervical Rib	5
Cervical Laminectomy	9
Carpal Tunnel	5
Prior Surgery, 25 patients	33

TABLE 2

CLINICAL FINDINGS

Symptoms	No. of patients
Neck, Shoulder, Arm Pain	115
Numbness and Paresthesias of Arm	99
Positional Effects of Arm	90
Motor Weakness	24
Headache	30
Signs	
Vascular	
Pulse Obliteration	92
Neurologic	
Muscle Atrophy	17
Objective Weakness	36
Dystrophic Changes	14

The use of the Adson sign and the policeman's stop position sign, although gross evaluations of the state of the peripheral circulation, are still of use in evaluating the entire patient. It is our feeling that expensive and detailed Doppler evaluation is not necessary, as the change in pulse pressure as the positions are assumed, gives us excellent clinical correlation with symptoms. An interesting observation was that cervical traction characteristically exacerbated the symptoms of TOS.[1]

Ancillary Diagnostic Methods

Chest x-ray, selective subclavian arteriography, and electromyography were often helpful in corroborating the clinical diagnosis of TOS, as shown in Table 3. Selective subclavian arteriography was performed on 70 patients and was positive in 42. This procedure was especially valuable when vascular problems, such as post-stenotic dilatation of the subclavian artery was suspected.[3]

Chest x-ray was valuable in demonstrating cervical ribs, synostosis or bifid first rib, or clavicular fractures. Ten of our series had cervical ribs, all of which were successfully resected from below.

Electromyography was abnormal in 62 of the 90 patients in whom it was performed. The ulnar nerve distribution was most commonly affected, the median and radial nerves being seldom involved except in recurrent cases. The EMG was helpful in ruling out carpal tunnel syndrome and ulnar nerve entrapment at the elbow when any question existed as to the definitive diagnosis of TOS.

These ancillary diagnostic tests were most often used in cases in which litigation was either pending or expected. This is because of the difficulties of presenting a clinical diagnostic entity to a jury; they comprehend pictures and numbers much better. Twenty-eight patients had EMGs and selective subclavian arteriograms, but with an obvious clinical diagnosis of TOS. In this sub-set, 26 patients had excellent results in long-term follow-up (two to six years), demonstrating again the clinical nature of the diagnosis.

In conclusion, all of our patients were referred from orthopedists, vascular surgeons, neurologists, and neurosurgeons. All patients had x-rays of the cervical spine and careful examinations for disc or spinal cord disease. When any question existed, CT scan and myelograms were performed before referral so that our referral population was essentially free of proximal cervical pathology. EMG when indicated helped with distal entrapment syndromes if confusion existed.

TABLE 3

ANCILLARY METHODS OF DIAGNOSIS

Roentgenographic Findings	No. of patients
Cervical Rib	10
Synostosis	8
Fractured Clavicle	6
Arteriography (70)	
Compression	21
Compression with Abduction	42
Normal	28
Electromyography (90)	
Slow	40
Marked Slowing	22
Normal	28

Philosophy and Operative Technique

When first seen, the majority of our patients have undergone almost all possible routes of conservative therapy. We feel that to repeat these modalities of treatment is a useless waste of valuable time and energy. Once the diagnosis of TOS is confirmed on a clinical basis, using the ancillary diagnostic methods in certain selected groups, surgery is recommended.

The operative technique is the standard transaxillary approach using scrupulous hemostasis, subperiosted resection of the first rib, and identification and lysis of all fibrous bands, possibly compressing the neurovascular bundle.

Results

As previously mentioned, 115 patients underwent 122 transaxillary first rib resections. Four patients had bilateral resections at the same time and three had staged bilateral resections. All patients were followed up by office visit or phone interview. The period of follow-up was six months to 16 years, with 85% of the patients over two years post operative. Many detailed follow-up evaluation systems have been devised in medicine, but we believe that overall patient satisfaction with the result means much more to the reader than a system of 1+ to 4+. The major method of evaluation used was the question, "Are you improved over your preoperative condition, and would you undergo the surgery again?"

Of the 115 patients, 103 answered yes to both of these questions. Headache, a troublesome symptom, was relieved permanently in 20 of 30 cases. Residual symptoms were seen in 20% of the patients, as shown in Table 4. Most were related to stormy weather conditions or position of the extremity. Most common was paresthesia with neck, shoulder, and arm pain. We feel the incidence of residual symptomatology was directly related to the time interval from onset of symptoms to definitive decompression. In spite of residual symptoms, most of these patients considered themselves substantially improved. Constant nerve compression caused pressure necrosis and scarring, which cannot be helped in the late stages by simple decompression. Permanent disability is the result.

Complications are shown in Table 5. There were no deaths, no vascular or brachial plexus injuries, and two wound infections, which cleared with conservative measures of antibiotics and warm compresses. There were two instances of pneumothorax, one requiring chest tube insert and the other resolving spontaneously in three days. The average post operative stay in unilateral patients was 2.5 days, down from 3.5 days in the original series. Most patients returned to work in two weeks, and one obstetrician delivered a baby on his fifth post operative day.

Discussion

Information pertinent to the diagnosis and treatment of severe TOS is still incompletely disseminated, much less accepted by the medical community. Because litigation is either underway or in the offing in many trauma-related cases, physicians often feel threatened when confronted by a dissatisfied, often hostile individual, complaining bitterly of shoulder and arm pain, and often shy away from involvement. These patients are characteristically passed from one physician to another without benefit of diagnosis, much less effective treatment, often finding themselves in the care of our psychiatric friends or in the offices of the chiropractor. This calamity is compounded at home as friends and family grow fatigued by the constant complaints and sympathy thus ceases.[4] It is of no wonder that an obvious emotional element is characteristically entwined with the vascular or neural elements of the shoulder girdle.

Many of these patients have been both physically and emotionally derailed from the mainstream because of chronic pain and multiple unsuccessful physician consultations. It is hoped that we are contributing to more accurate recognition of the problem and thus more rapid and definitive diagnosis and treatment. In practice, referrals for surgery are made due to failure of multiple non-operative therapies which have usually been tried for months to years. To arbi-

TABLE 4

Residual Symptoms	No. of patients
Paresthesia	25
Neck, Shoulder, Arm Pain	12
Hyperesthesia	6
Chest Pain	10
Sympathetic Overplay	7
Headache	8

TABLE 5

Complications	No. of patients
Death	0
Wound Infection	2
Pneumothorax	2 (1 required chest tube)
Brachial Plexus or Subclavian Vessel Injury	0
Long Thoracic Nerve Palsy	0

trarily demand another period of discomfort before surgery is ill advised. The theory that we should await the completion of litigation as a prerequisite for surgical decompression is inexcusable. We personally feel that the diagnosis of TOS is a clinical one. Angiography and electro-diagnostic studies are certainly not needed in all patients who have the typical signs and symptom complex. The ancillary tests should be reserved for the more complicated and often the trauma and work-related injury cases in which "objective findings" would help in defending a position in court.

Bilateral involvement is not unusual. However, we recommended surgery on both sides in only seven patients in our series. Often decompression of one side caused such improvement that the opposite side became more tolerable. Improvement of postural dynamics probably comes into play in this situation. We feel bilateral resections are sometimes indicated and can be done safely at one time without added complications, as we did in four cases.

Only one case of subclavian vein involvement for an incidence of less than 1% was seen in this series.[5] A 24 year old man presented with complete thrombosis of the subclavian-axillary vein complex. He was initially treated by intravenous enzymatic dissolution of the clot, followed by intravenous heparin drip. After ten days the swelling completely disappeared and he was converted to Coumadin. Four weeks later he underwent bilateral first rib resections during one operation without complication. He is now symptom-free, without sequellae, after 18 months.

Operative injury to the neurovascular bundle has not occurred in our series. Recently, Cherengton, et al, have published a scathing incrimination of the surgical handling of TOS.[6] We agree that complications such as he reports are regrettable and preventable; however, fear of complication in competent surgical hands with a proven track record is a poor reason to withhold therapy. Obviously, the diagnosis must be correct or acceptable operative results will not be forthcoming either in the short or long term.

Causalgia with sympathetic overplay in cases of chronic neglected TOS is not uncommon. Chronic throbbing pain and marked sensitivity to cold are the cardinal symptoms. The hair standing on end is often seen as the extremity is examined. Drug addiction can easily occur as chronic pain, without explanation, leads to more and more narcotic use. Thoracic sympathectomy has been necessary in eight of our cases following incomplete resolution of symptoms after first rib resection. We do not feel that the sympathetic dystrophy seen in these cases postoperatively was due to operative injury, but due to pre-existing chronic compression and pain. In cases of long-standing TOS with symptoms of sympathetic overplay, we are now considering concomitant first rib resection and thoracic sympathectomy via the same transaxillary approach as recommended by Roos.[5]

Proximal propagation of symptoms including shoulder girdle, cervical and trapezius pain, along with cluster headache is not uncommon. This may be due simply to deranged skeletal dynamics or to proximal propagation along standard neural pathways from the point of compression injury. Our experience has shown marked improvement in these proximal symptoms as demonstrated by Roos,[5] Lord,[7] and others.

Recurrent symptoms after a good initial result are often troublesome. This may be due to an excessively vigorous return to full mobility in an extremity which has been disabled for months to years with its natural concomitant muscle and joint soreness. This problem generally passed with the institution of the "quiet convalescence" as advised by Roos.[5] A major problem is recurrence due to reattachment by scar of the scalene musculature to the neurovascular bundle itself.[8] These recurrent symptoms characteristically involve the medial nerve distribution while the original symptoms were primarily ulnar in distribution. A supraclavicular approach with neurolysis and complete resection of all muscle and ligamentous attachments was performed in two of these patients at four and 16 months respectively. The results of this second operation were satisfactory.

Summary

One hundred fifteen patients underwent 122 transaxillary resections of the first rib for thoracic outlet syndrome. The diagnosis of TOS is primarily clinical. Ancillary tests such as selective subclavian arteriography and electromyography are reserved for cases with legal implications or in complicated cases where specific information is needed, ie, arterial insufficiency or embolism.

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MEDICAL LEGAL CASE CONFERENCE: THE DOCTRINE OF INFORMED CONSENT

David E. Raskin, M.D.

Case Presentation

The patient was a 66 year old white woman who suffered from cancer of her jaw and gangrene of her left hand. She refused medical treatment for a number of months. Her family became increasingly concerned over her condition. Upon admission to the Wilmington Hospital surgical service, she refused any treatment, including the insertion of an intravenous line or oxygen. She indicated that she would sue any doctor who attempted to treat her. Her family noted that over the past few months she had consistently denied having any medical illness and refused any treatment. On interview, the patient disclaimed medical problems and stated that she wanted to go home. She seemed unaware of the nature of her medical condition and refused to participate in a discussion of diagnostic and treatment alternatives, risks, and benefits.

The questions which need to be answered are these:

1. Is this patient capable of providing informed consent or informed refusal?
2. What is informed consent as defined by Delaware Code?
3. What are the exceptions to obtaining informed consent?
4. What is the protocol for handling a patient such as this?

The doctrine of informed consent requires a physician to disclose information regarding treatment and to obtain consent to perform such treatment. The information about treatment procedures or surgery must be information customarily given to patients by other licensed health care providers with similar training and/or experience in the same or similar health care communities. In other words, a professional practice standard relevant to what reasonable practitioners in the community do is required in order to meet the information requirement of informed consent. It is important to note that not only is the physician required to provide information about procedures to be performed, but the patient must also be afforded information about the risks and benefits of deciding against having a procedure performed. For example, in the landmark case of Truman v. Thomas, the patient was not informed about the possible risks of refusing a Pap smear. The physician was found libelous for failure to provide information when the patient developed a cervical carcinoma.

The exceptions to informed consent include a patient not competent to provide informed consent, an emergency, a patient waiving consent, and therapeutic privilege. In Delaware, therapeutic privilege permits a health care provider to limit the extent of his or her disclosure to the patient if such disclosures could be expected to affect adversely and substantially the patient's condition or the outcome of the treatment procedure or surgery. It is recommended that physicians consult with the hospital attorney before invoking the therapeutic privilege.

In the patient discussed here, the relevant exception would be competency. Note that

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competency does not require the presence of a physician or psychological impairment. Competency refers to a number of issues, including the patient stating a choice, the choice appearing to be reasonable, the choice being rational, the patient's understanding, risks, benefits, and alternatives to treatment. The risks, benefits, and alternatives criteria for competency is the one that is most consistent with law regarding informed consent. In many situations, consent by a family is considered appropriate in a non-competent patient, providing the patient does not evidence clear dissatisfaction or negative feelings towards the treatment. In the circumstances noted here, the patient clearly indicated she did not want the treatment performed. In this circumstance, in spite of the family's wishes, it was felt by the hospital attorneys that the Court of Chancery should make a decision regarding the patient's competency and subsequent treatment.

The court decided that the relevant criterion would be understanding of risks, benefits, and consequences of treatment. The court found that the patient was not of sufficient mind to understand the risks and benefits of treatment, and further held that irrationality alone is sufficient to justify incompetence even in the absence of a clear etiology. The court decided that whatever diagnosis and treatment was necessary to ameliorate suffering could be performed. A decision about possible surgery for her gangrene was deferred. The patient died nine days later.

Summary

Informed consent requires permission from patients for procedures and treatment, subsequent to the patient's being provided with an appropriate knowledge base by the attending physician. In the protesting patient described, the case was taken to the Court of Chancery, which decided that risks, benefits, alternatives, and consequences would be the appropriate criteria for her case. In general, in non-protesting patients, with consistent family support for treatment, documented consent by the family is sufficient. However, in those cases in which there is family conflict and/or the patient clearly refuses to have the treatment performed, it is advisable to call an attorney in order to decide whether the case needs to be taken to court.

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*These citations refer to the Principles of Medical Ethics which may be found in the rear of the 1987-1988 Pictorial Roster of the Medical Society of Delaware

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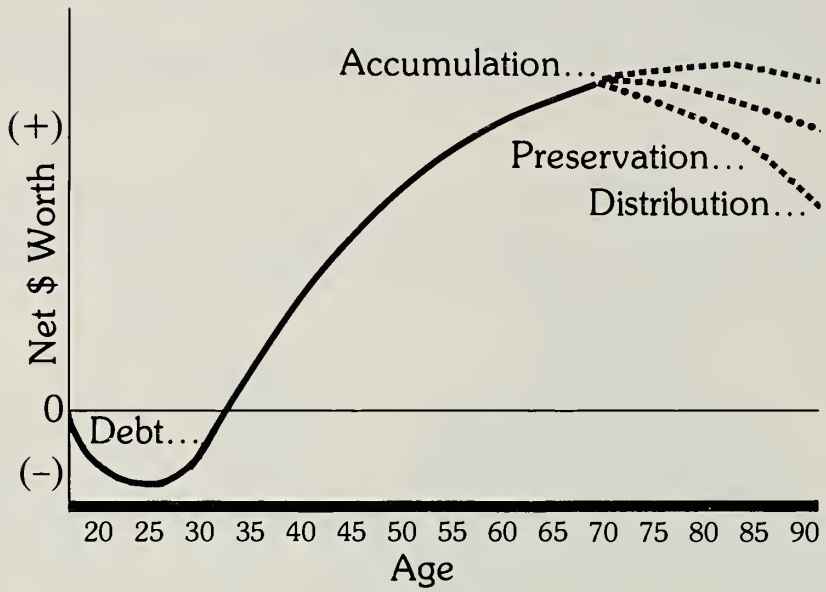

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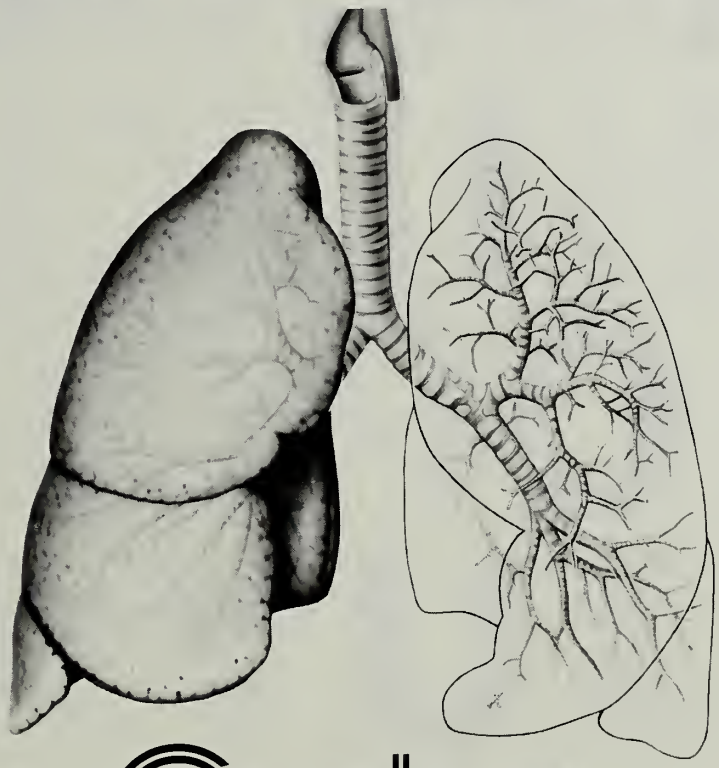

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Administer cautiously to allergic patients.
Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics. It must be considered in differential diagnosis of antibiotic-associated diarrhea. Colon flora is altered by broad-spectrum antibiotic treatment, possibly resulting in antibiotic-associated colitis.

Precautions:
- Discontinue Ceclor in the event of allergic reactions to it.
- Prolonged use may result in overgrowth of nonsusceptible organisms.
- Positive direct Coombs' tests have been reported during treatment with cephalosporins.
- Ceclor should be administered with caution in the presence of markedly impaired renal function. Although dosage adjustments in moderate to severe renal impairment are usually not required, careful clinical observation and laboratory studies should be made.
- Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.
- Safety and effectiveness have not been determined in pregnancy, lactation, and infants less than one month old. Ceclor penetrates mother's milk. Exercise caution in prescribing for these patients.

Adverse Reactions: (percentage of patients)
Therapy-related adverse reactions are uncommon. Those reported include:
- Gastrointestinal (mostly diarrhea): 2.5%.
- Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment.
- Hypersensitivity reactions (including morbilliform eruptions, pruritus, urticaria, and serum-sickness-like reactions that have included erythema multiforme [rarely, Stevens-Johnson syndrome] or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever): 1.5%; usually subside within a few days after cessation of therapy. Serum-sickness-like reactions have been reported more frequently in children than in adults and have usually occurred during or following a second course of therapy with Ceclor. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.
- Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.
- As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely.
- Rarely, reversible hyperactivity, nervousness, insomnia, confusion, hypertonia, dizziness, and somnolence have been reported.
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IS COURTESY OLD HAT?

It's time to air my pet peeve.

Once upon a time, most physicians were polite to each other. A certain air of camaraderie and gentility cemented a practitioner of the art to his colleagues. I mourn the passage of those golden days. Today, not only do the laity hold physicians in poor regard, but their colleagues often do the same.

It strikes me that when a consultant is asked to see a patient, it is the requesting physician who wants the information. It is the requesting physician who has the privilege of asking for other consultations and opinions. It is not the privilege of the consultant to call in a second consultant. In truth, unless the requesting physician specifically asks the consultant to "take over" the case, he is asking for an opinion only. The consultant should communicate his opinion to the requesting physician and *not* make statements to the patient or family that commit the requesting physician to a course of action with which he may not agree.

There also was a time when no attending physician would have dreamed of asking house officers to contact a consultant to see his patient. Attendings would have had the courtesy to contact the second physician himself. That nicety seems to take too much time now.

Can you give me one good reason why any physician should write illegibly on a hospital chart? After all, the purpose for chart notes is to keep track of all that occurs to the patient in the hospital, not only for the attending but for every professional who must read the chart. The purpose of writing is to convey a message. Chicken scratches may convey messages to chickens, but not to health care professionals. I know the usual excuses: "I've always had bad handwriting," or "I don't have time to write any better."

Behind these gossamer alibis hides a scintilla of pride, of glory in being the busy, demanded practitioner, too busy to think of others. In truth, the real reason is a blatant disregard for the feelings of the poor soul forced to decipher the encoded cryptogram. The scribbler is, in truth, saying, "My time is more valuable than yours. I don't have time to write legibly, but you have time to try to figure out what I wrote." The only reason for writing is to communicate a message, an idea. For Pete's sake: if you don't want to take the time to write so it can be read, don't insult us by doing it at all!

It doesn't end there. When Dr. A asks his secretary to call Dr. B, should Dr. B have to hang on the phone while Dr. A's secretary sets out to find the rude doctor? If Dr. A had wanted to talk to Dr. B, why isn't he on the phone when Dr. B picks it up? Dr. A, who probably also writes illegibly, is telling Dr. B, "Look, B, I want to talk to you but my time is too valuable to hang on while you're being sought. You hang on the phone. Your time is less valuable than mine. When you have picked up the phone, I'll condescend to speak with you, if I can be found."

Do any of you remember the days when a physician would drop whatever he was doing to answer the call of another physician? There was a

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ARMY MEDICINE. BE ALL YOU CAN BE.

time that no physician was too busy to take the phone call immediately. Today, one is apt to hear an imperious nurse respond to the calling physician, "His Highness has just gone in to do a history and physical. He can't take the phone now."

When asked to see a physician or any family member, I make it a point to see that physician or family member on the day of the call. He is taken immediately into my consultation room, and thence, into an examining room, if necessary. That courtesy isn't prevalent today. One of the privileges of getting to be a senior physician today is the privilege of sitting in waiting rooms for what seems to be hours at a time, wondering why some physicians make any appointments at all.

Oh, but the old days were warm and glorious. Please forgive an oldtimer his reminiscences.

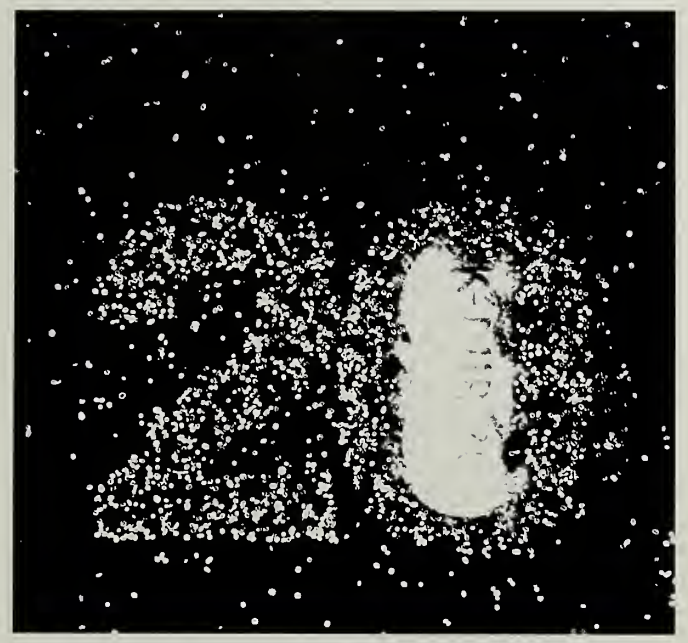
Carl Glassman, M.D.

COMMON DIAGNOSTIC TESTS: THE BOOK AND THE PROBLEM

Common Diagnostic Tests: Their Use and Interpretation,[1] may have been one of the most important books published in 1987 since it has been rumored that the mighty Blues are getting ready to use the suggestions therein as clinical rules for reimbursability for laboratory tests. If and when this happens, tests ordered in excess of those recommended in the various chapters by these particular experts will not be reimbursed by Blues' insurance plans, and conversely, tests not performed will be considered a sign of inept management.

Of particular and ironic interest is that the series was actually commissioned by the Blue Cross and Blue Shield Association, and then published in the prestigious *Annals of Internal Medicine*. Although the *Annals* subjected each paper to its usual vigorous peer review, some of the recommendations may appear didactic or inappropriately stringent to those with deliberately thought-out patterns of their own. Now the American College of Physicians, sponsors of the *Annals* in which the various chapters of *Common Diagnostic Tests* first appeared, is requesting its members to report to it any third party payers attempting to use as Medical Necessity Guidelines or "inflexible standards for reimbursement"[2] material from this book.

The introduction is an excellent review of that all-important Bayse's theorem which "often provides insights that are not obtained by relying on intuition." We are also reminded that "the interpretation of a test result depends on the pretest probability of disease," a concept of great relevance to the current HIV testing debate. The



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INDICATIONS AND USAGE: BECAUSE OF REPORTS OF INTESTINAL AND GASTRIC ULCERATION AND BLEEDING WITH SLOW-RELEASE POTASSIUM CHLORIDE PREPARATIONS, THESE DRUGS SHOULD BE RESERVED FOR THOSE PATIENTS WHO CANNOT TOLERATE OR REFUSE TO TAKE LIQUID OR EFFERVESCENT POTASSIUM PREPARATIONS OR FOR PATIENTS IN WHOM THERE IS A PROBLEM OF COMPLIANCE WITH THESE PREPARATIONS.

1. For therapeutic use in patients with hypokalemia with or without metabolic alkalosis, in digitalis intoxication and in patients with hypokalemic familial periodic paralysis.

2. For the prevention of potassium depletion when the dietary intake is inadequate in the following conditions: Patients receiving digitalis and diuretics for congestive heart failure, hepatic cirrhosis with ascites, states of aldosterone excess with normal renal function, potassium-losing nephropathy, and with certain diarrheal states.

3. The use of potassium salts in patients receiving diuretics for uncomplicated essential hypertension is often unnecessary when such patients have a normal dietary pattern. Serum potassium should be checked periodically, however, and if hypokalemia occurs, dietary supplementation with potassium-containing foods may be adequate to control milder cases. In more severe cases supplementation with potassium salts may be indicated.

CONTRAINDICATIONS: Potassium supplements are contraindicated in patients with hyperkalemia since a further increase in serum potassium concentration in such patients can produce cardiac arrest. Hyperkalemia may complicate any of the following conditions: Chronic renal failure, systemic acidosis such as diabetic acidosis, acute dehydration, extensive tissue breakdown as in severe burns, adrenal insufficiency, or the administration of a potassium-sparing diuretic (e.g., spironolactone, triamterene).

Wax-matrix potassium chloride preparations have produced esophageal ulceration in certain cardiac patients with esophageal compression due to enlarged left atrium.

All solid dosage forms of potassium chloride supplements are contraindicated in any patient in whom there is cause for arrest or delay in tablet passage through the gastrointestinal tract. In these instances, potassium supplementation should be with a liquid preparation.

WARNINGS: Hyperkalemia—In patients with impaired mechanisms for excreting potassium, the administration of potassium salts can produce hyperkalemia and cardiac arrest. This occurs most commonly in patients given potassium by the intravenous route but may also occur in patients given potassium orally. Potentially fatal hyperkalemia can develop rapidly and be asymptomatic. The use of potassium salts in patients with chronic renal disease, or any other condition which impairs potassium excretion, requires particularly careful monitoring of the serum potassium concentration and appropriate dosage adjustment.

Interaction with Potassium Sparing Diuretics—Hypokalemia should not be treated by the concomitant administration of potassium salts and a potassium-sparing diuretic (e.g., spironolactone or triamterene) since the simultaneous administration of these agents can produce severe hyperkalemia.

Gastrointestinal Lesions—Potassium chloride tablets have produced stenotic and/or ulcerative lesions of the small bowel and deaths. These lesions are caused by a high localized concentration of potassium ion in the region of a rapidly dissolving tablet, which injures the bowel wall and thereby produces obstruction, hemorrhage or perforation.

K-DUR tablets contain micro-crystalloids which disperse upon disintegration of the tablet. These micro-crystalloids are formulated to provide a controlled release of potassium chloride. The dispersibility of the micro-crystalloids and the controlled release of ions from them are intended to minimize the possibility of a high local concentration near the gastrointestinal mucosa and the ability of the KCl to cause stenosis or ulceration. Other means of accomplishing this (e.g., incorporation of potassium chloride into a wax matrix) have reduced the frequency of such lesions to less than one per 100,000 patient years (compared to 40–50 per 100,000 patient years with enteric-coated potassium chloride) but have not eliminated them. The frequency of GI lesions with K-DUR tablets is, at present, unknown. K-DUR tablets should be discontinued immediately and the possibility of bowel obstruction or perforation considered if severe vomiting, abdominal pain, distention, or gastrointestinal bleeding occurs.

Metabolic Acidosis—Hypokalemia in patients with metabolic acidosis should be treated with an alkalinizing potassium salt such as potassium bicarbonate, potassium citrate, potassium acetate, or potassium gluconate.

PRECAUTIONS: The diagnosis of potassium depletion is ordinarily made by demonstrating hypokalemia in a patient with a clinical history suggesting some cause for potassium depletion. In interpreting the serum potassium level, the physician should bear in mind that acute alkalosis per se can produce hypokalemia in the absence of a deficit in total body potassium while acute acidosis per se can increase the serum potassium concentration into the normal range even in the presence of a reduced total body potassium. The treatment of potassium depletion, particularly in the presence of cardiac disease, renal disease, or acidosis requires careful attention to acid-base balance and appropriate monitoring of serum electrolytes, the electrocardiogram, and the clinical status of the patient.

Laboratory Tests: Regular serum potassium determinations are recommended. In addition, during the treatment of potassium depletion, careful attention should be paid to acid-base balance, other serum electrolyte levels, the electrocardiogram, and the clinical status of the patient, particularly in the presence of cardiac disease, renal disease, or acidosis.

Drug Interactions: Potassium-sparing diuretics; see **WARNINGS.**

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term carcinogenicity studies in animals have not been performed.

Pregnancy Category C: Animal reproduction studies have not been conducted with K-DUR. It is also not known whether K-DUR can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. K-DUR should be given to a pregnant woman only if clearly needed.

Nursing Mothers: The normal potassium ion content of human milk is about 13 mEq per liter. Since oral potassium becomes part of the body potassium pool, so long as body potassium is not excessive, the contribution of potassium chloride supplementation should have little or no effect on the level in human milk.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: One of the most severe adverse effects is hyperkalemia (see **CONTRAINDICATIONS, WARNINGS,** and **OVERDOSAGE**). There have also been reports of upper and lower gastrointestinal conditions including obstruction, bleeding, ulceration, and perforation (see **CONTRAINDICATIONS** and **WARNINGS**); other factors known to be associated with such conditions were present in many of these patients.

The most common adverse reactions to oral potassium salts are nausea, vomiting, abdominal discomfort, and diarrhea. These symptoms are due to irritation of the gastrointestinal tract and are best managed by taking the dose with meals or reducing the dose

Skin rash has been reported rarely.

OVERDOSAGE: The administration of oral potassium salts to persons with normal excretory mechanisms for potassium rarely causes serious hyperkalemia. However, if excretory mechanisms are impaired or if potassium is administered too rapidly intravenously, potentially fatal hyperkalemia can result (see **CONTRAINDICATIONS** and **WARNINGS**). It is important to recognize that hyperkalemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration and characteristic electrocardiographic changes (peaking of T-waves, loss of P-waves, depression of S-T segment, and prolongation of the QT-interval). Late manifestations include muscle-paralysis and cardiovascular collapse from cardiac arrest.

Treatment measures for hyperkalemia include the following:

1. Elimination of foods and medications containing potassium and of potassium-sparing diuretics

2. Intravenous administration of 300 to 500 ml/hr of 10% dextrose solution containing 10–20 units of insulin per 1,000 ml.

3. Correction of acidosis, if present, with intravenous sodium bicarbonate.

4. Use of exchange resins, hemodialysis, or peritoneal dialysis.

In treating hyperkalemia, it should be recalled that in patients who have been stabilized on digitalis, too rapid a lowering of the serum potassium concentration can produce digitalis toxicity

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book, however, is incomplete. There are no chapters on endocrine, ie, thyroid testing, nor on other clinical tests such as Pap smears, colposcopies, mammograms, etc, but can those chapters be far behind?

"A profession is defined in part by whether it commits itself to setting standards for the services society expects. The esteem society holds for a profession is determined largely by what standards it sets and how closely it meets them. One often professed standard in medicine is providing the best possible care at the lowest price," say Drs. Sox and Huth in the preface. I don't believe the "lowest price" for care used to be so universally part of our primary standards, but, apparently, it is now. Do our patients know?

Dr. Sox from Stanford, and Dr. Huth, editor of the *Annals of Internal Medicine*, invite communication about this manual to be sent to Dr. Huth. I suggest that concerned clinicians who may well have to live with and by these clinical laboratory utilization interpretations read the book and respond to Dr. Huth's invitation; a newer revised edition is already underway.

Bernadine Z. Paulshock, M.D.

References

1. Sox HC. Common diagnostic tests: use and interpretation. Philadelphia: American College of Physicians, 1987.

2. Martz EW, ACP Governor for Delaware. Governor's newsletter. January 1988:2.

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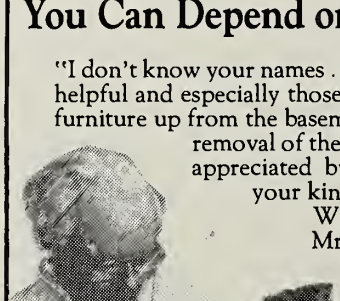
Mrs. John P. McCormick



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THE "CRACK" IN THE EMERGENCY ROOM DOOR

In the beginning, Yvonne was just an abstraction on the Emergency Department radio to me. I took the call one afternoon last summer.

"We have a woman in her 30s," the EMT in the field reported. "She's conscious, combative and needs restraints."

On the upper level of a Victorian style house, she had injected herself with crack, the most potent form of cocaine.

When I examined Yvonne, she responded to stimuli only slightly. Pain would cause a withdrawal movement that was incomplete but identifiable. Her irises were thin rims around widely dilated pupils that reacted sluggishly to light. Her breathing was deep and rapid. Barely present at her wrists was a rapid, shallow pulse.

The results of her lab work painted a grim picture. The ECG showed that her heart was severely compromised. Also grim were the numbers that showed moderate kidney failure and liver dysfunction. We were faced with multiple organ failure, changes in mental status, and poisoning from crack.

Modern medicine offered me few weapons with which to fight Yvonne's problem. I felt helpless and frustrated. We did what we could, but it made no difference in her immediate condition. Within 36 hours of injecting herself, she could no longer breathe without a respirator and her prognosis was grave. Three days later, in the intensive care unit, she died.

Yvonne had been careful with her injection. Her husband told me that the two of them had never used crack before, and that they had little idea of how easy it was to overdose. They had used cocaine several times with no side effects, and they had gradually increased their use of the drug. To them, the world seemed a happier, more exciting place when they used cocaine. It couldn't harm them, they thought, because they were so young and healthy.

Yvonne never had a chance to understand what hit her. She never stood outside herself to see the decline from abuse to addiction to death. Her plight resembled that of the trauma patient who is in a coma from the moment of impact. Her chances of survival, however, were considerably worse.

I found it disconcerting and distressing to deal with the inevitable death of a productive person who abused herself. Yvonne found drugs more fun than reality. Her death reminded me that drug abuse is a disease of our society. Realizing that was bitter medicine.

Daniel G. Sayers, M.D.

Dr. Sayers is an assistant professor in the Section of Emergency Medicine of the Department of Surgery at Bowman Gray School of Medicine, Winston-Salem, North Carolina. Reprinted with permission by *North Carolina Medical Journal*, 1987; 48(7):410.

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Medical Society of Delaware Insurance Services, Inc., reports as follows:

1. On the preceeding page appears an advertisement from Continental Casualty Companyu. The suggestion is made, implicitly, that Continental Casualty Company may be a new source of professional liability insurance.

Continental Casualty Company has told us that it will not sell insurance through Medical Society of Delaware Insurance Services, Inc.

We understand Continental Casualty Company has not offered a long term commitment to continue to provide professional liability insurance in the state.

.2 The Department of Insurance of the State of Delaware recently received a notice from a Delaware physician that he had been contacted by Professional Risk Insurers Management Exclusive Company, Inc. ("P.R.I.M.E."). P.R.I.M.E. has no administrative office in the United States and operates from a Chicago post office box. The Cook County, Illinois Circuit Court has enjoined the company from operating in Illinois. In addition, the U.S. Postal Service has issued an injunctive order against this company. If this "company" acts true to form, it will continue to solicit doctors in Delaware. Should you be contacted by P.R.I.M.E. or any other insurance company, call the Medical Society of Delaware.

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WEDNESDAY, JUNE 1, 1988

MEDICAL ECONOMICS - THE FINANCIAL PLIGHT OF THE DOCTOR

MODERATOR: Bernard L. Segal, M.D.

3:00 to 3:20	Influence of DRG's - I. Donald Snook
3:20 to 3:40	Influence of For-profit Systems, HMOs, PPOs, etc. I. Donald Snook
3:40 to 4:00	Solo Versus Group Practice Robert Stein, Ph.D.
4:00 to 4:20	Town and Gown Conflict: Fact or Fiction? Bernard L. Seagal, M.D.
4:20 to 5:00	Panel Discussion Morton Shrager, M.D., Charles A. Syms, M.D.

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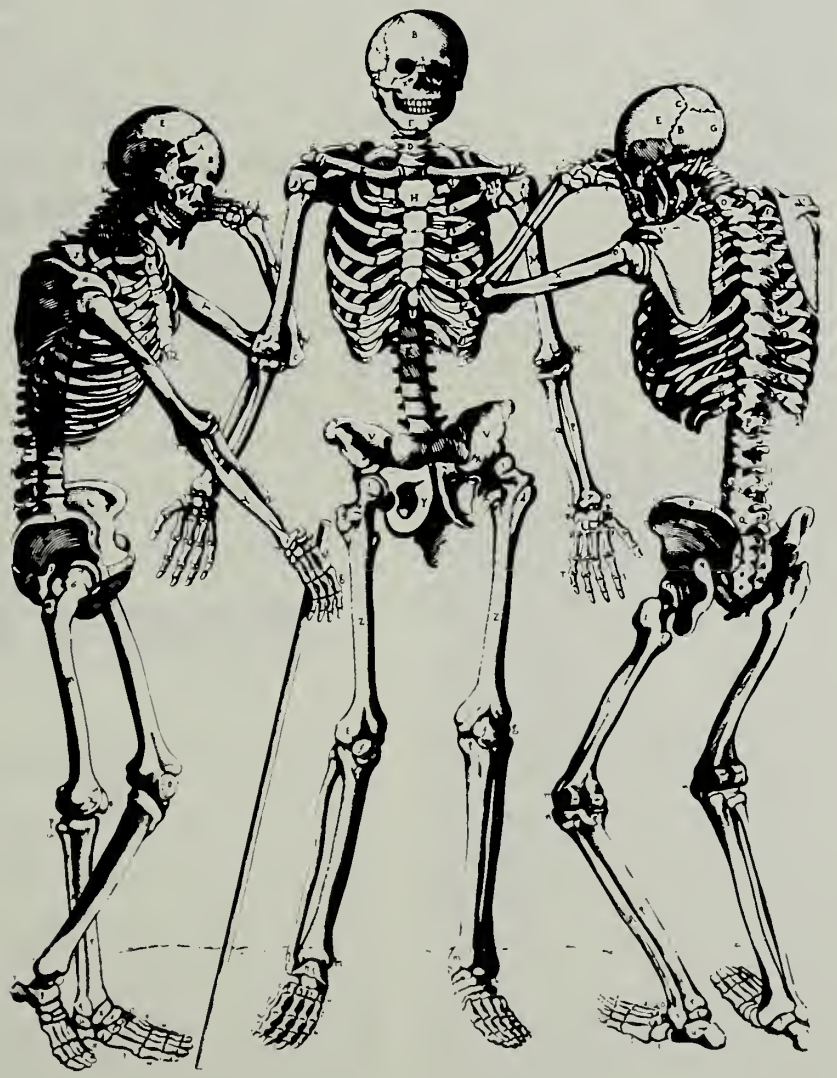
In Black and White

Dennis R. Witmer, M.D. Photographic Editor



The Accessory Figures from *Tabulae anatomicae a celeberrimo pictore Petro Berrettimo Cortonensi delineatae, et egregie aeri incisae nunc primum prodeunt, et a Caietano Petrioli Romano ... notis illustratae.* Rome, A. de Rubeis for F. Amidei, 1741.

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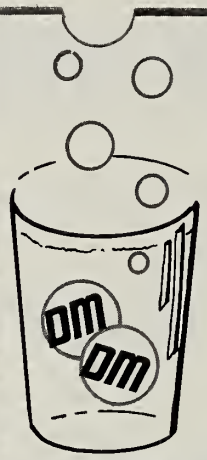

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In Brief

PHYSICIAN'S HEALTH COMMITTEE

DO YOU KNOW AN IMPAIRED PHYSICIAN OR A PHYSICIAN IN TROUBLE? The Physician's Health Committee wishes to help. Please call 302-654-1001. The anonymity of the caller is assured.

CLINICAL MEETINGS AND NOTICES

ANESTHESIOLOGY UPDATE: 1988

Pediatric intensive care, pediatric problem patients, and problems with hypothermia are some of the topics to be discussed at the Anesthesiology Update: 1988, to be held at Colby College in Waterville, Maine on July 25-28. Up to 15 hours of Category 1 credit will be offered. For more information, call the Division of Special Programs at 207-872-3386.

ASTHMA AND ALLERGY UPDATE

Colby College in Waterville, Maine, will be hosting an Asthma and Allergy Update July 25-29, 1988. Practical aspects of diagnosing and managing patients with asthma, allergic rhinitis, insect sting allergy, etc, will be discussed. Up to 16 Category 1 credits will be offered. For more information, call the Division of Special Programs at 207-872-3386.

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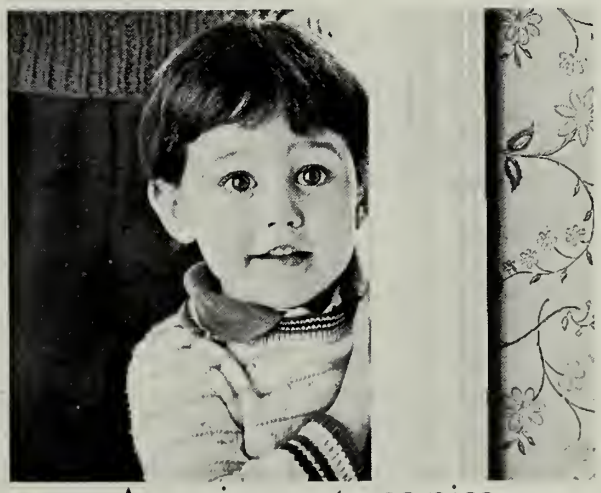

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BERKSHIRE AREA HEALTH EDUCATION CENTER

The Fourth Annual Berkshire Medical Conference, co-sponsored by University of Massachusetts Medical School, Berkshire Medical Center, and Berkshire Area Health Education Center (AHEC), will he held during July, 1988. Course offerings include "Advances in Cardiology," July 14-16, and "Special Challenges in General Medicine," July 21-23. Geared to the primary care physician, these courses will present updates on the latest information critical to the office-based management of cardiac problems, and to special problems in primary care. Up to 30 hours of Category 1 credits will be offered for attending both courses. For more information, call Berkshire AHEC at 413-447-2417.

COMPUTER APPLICATIONS IN RADIOLOGY

Hilton Head Island will be the site of the Ninth Annual Conference on Computer Applications in Radiology on June 1-4, 1988. Up to 21 hours of Category 1 credit will be offered. For more information, contact Janice Ford, Continuing Education Advisor, Department of Radiology, Hospital of the University of Pennsylvania, 3400 Spruce Street, Philadelphia, Pennsylvania, 19104, or call 215-662-6904.

DIABETES CONFERENCE

The Delaware Division of Public Health is sponsoring a Statewide Diabetes Conference on June 15, 1988, 4-8 p.m. at the Sheraton Inn in Dover. The featured speaker is Arthur Krosnik, M.D., Medical Director of the Princeton Diabetes Treatment and Education Center. For more information, contact Lori Christensen at 736-4745.

EASTERN SHORE MEDICAL SYMPOSIUM

The 11th Annual Eastern Shore Medical Symposium, jointly sponsored by Jefferson Medical College, the University of Delaware, and the Medical Society of Delaware, will be held June 20-26, 1988, in Rehoboth Beach, Delaware. A total of 22 Category 1 credit hours will be offered for the program. Registration should be made by June 6, 1988. For more information, contact the University of Delaware, 2800 Pennsylvania Avenue, Wilmington, Delaware, 19806.

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President's Page

PROTECTED PEER REVIEW

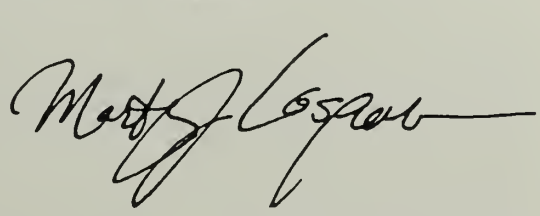
In recent years, the medical community has become increasingly sensitive to the potential liabilities which attach to participation in peer review. This concern was highlighted a short time ago when the United States Supreme Court reinstated a more than two million dollar anti-trust award against members of an Oregon hospital peer review committee in the case of *Patrick v. Astoria Clinic*.

In order to combat the obvious chilling effect upon effective peer review, the Medical Society of Delaware has caused legislation (S.B. 475) to be introduced which would bring hospital, medical society, and health maintenance organization peer review committees in Delaware under the protection of the Federal Health Care Quality Improvement Act of 1986 (PL 99-660). This federal law has two broad purposes. First, to promote peer review by providing immunity from liability for good faith peer review actions. Second, the Act requires reporting of medical malpratice judgments or settlements and peer review actions to a federal clearinghouse. This law is to go into effect across the country in October of 1989. However, each state has the option of having the immunity provisions of this law go into effect earlier (or not at all). The legislation we propose would have the immunity protection become effective 60 days after the bill is signed by the governor.

The Health Care Quality Improvement Act of 1986 is intended to promote professional peer review by providing that a professional peer review body and its members shall not be liable under any law of the United States or of any state with respect to actions that committee takes in the reasonable belief that they were in the furtherance of quality health care. In order to enjoy this protection, the peer review committee must operate according to fair and reasonable notice and hearing standards. Also, peer review committees must make reports of certain of their actions to the State Board of Medical Practice, which in turn must make reports to a federal clearinghouse.

Even though the federal Act may require our hospital and Society peer review committees to alter their procedures to some extent, this seems a small price to pay when weighed against the protections this law provides.

This local protection would come through the passage of S.B. 475, which will be voted on in the legislature the last week in June. It is hoped that we will have the support of our legislators.



Martin J. Cosgrove, M.D.

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DELAWARE MEDICAL JOURNAL

VOLUME 60

JUNE 1988

NUMBER 6

MEDICAL GRAND ROUNDS: OLD PEOPLE AND SURGERY

Herbert J. Keating, III, M.D.

Case Presentation

Daniel Burge, M.D.

A.T., a 79 year old woman, presented with nausea, vomiting, and diffuse abdominal pain which had developed the day prior to admission and was associated with post prandial vomiting. She was unable to keep down liquids or solid food. She described the pain as "crampy," positional, and constant.

Her past medical history was significant for a gastric ulcer first diagnosed five years before for which she was being treated with cimetidine. No definite follow-up for ulcer healing was noted in the history. She also had hypertension controlled by hydrochlorthiazide. She had had a remote cesarean section and benign left breast mass removed. She smoked a pack of cigarettes a day and described herself as a "social" drinker. She led an active, independent, retired life.

On physical examination, she was in no acute distress. Her blood pressure was 100/75 mm Hg in both arms, supine; pulse was 100 beats per minute. Sitting, with her legs dangling, her blood pressure was 95 mm Hg systolic. She was afebrile, her head and neck exam were unremarkable. Cardiac examination showed the apical impulse in the anterior axillary line at the fifth intercostal space. There was a soft systolic murmur but no gallops. The abdomen was mildly distended, firm, and mildly tender throughout the mid-epigastrium and right upper quadrant. Mild guarding without rebound was noted initially. Rectal exam was negative.

Laboratory examinations revealed creatinine of 2.0 mg/dl, BUN of 32 mg/dl, and potassium of 3.3 mEq/L. White blood cell count was 7700 with 56% neutrophils, 28% band forms, and 1% metamyelocytes. Supine and upright films of her abdomen showed no air-fluid levels or dilated bowel loops, and were intially read as normal. Review by an attending radiologist on the following morning showed possible intraperitoneal air.

The patient initially had a nasogastric tube placed, and was given narcotics for pain relief. On the following day, she was found to have a more rigid abdomen with rebound and absent bowel sounds. An urgent surgical consultation was obtained, and at laparotomy performed the day after admission, a perforated gastric ulcer was found which was closed with an omental patch. The surgical procedure was performed without difficulty; however, a "great deal" of peritoneal fluid which was "bowel stained" was evident. She was discharged from the recovery room directly to a floor bed, and was placed on broad-spectrum antibiotics. The day after surgery she was relatively comfortable and afebrile. Her BUN was 55 mg/dl and her creatinine 2.4 mg/dl. Her sodium was 123 mEq/L.

Three days postoperation, her sodium was 125 mM/l, BUN was 51 mg/dl, and creatinine was 2.7 mg/dl. She experienced problems with hypotension and worsening renal failure. Chest x-ray done the day before her death showed a basilar opacity of the left lung consistent with pneumonia, which obscured the left hemidiaphragm. Five days postoperatively she had a cardiac arrest following prolonged hypotension and oliguria. No autopsy was obtained.

Discussion

Herbert J. Keating, III, M.D.

This patient illustrates the difficulties that we physicians have when our elderly patients have medical problems that lead them to surgery.

This patient had a perforated gastric ulcer, and yet had only moderate symptoms and no signs of an acute abdomen. Certainly, her white blood cell differential count indicated something serious was wrong, but it was not until free air was detected on her radiograph that the clinicians caring for her appreciated that she had a surgical problem. This scenario is not uncommon in the elderly patient, and illustrates half of the para-

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dox of the geriatric physical exam: acute illnesses may be present with minimal signs, while common physical findings in the elderly; eg, systolic murmurs, may suggest serious disease when, in fact, none exists.[1] Certainly a high index of suspicion for surgical disease needs to be maintained when an elderly patient presents with abdominal distress.[2,3]

After surgery was elected, this patient received less than intensive care. Despite initial hypotension, prerenal azotemia and free perforation, neither Swan-Ganz catheterization nor the intensive care unit were used, making postoperative management difficult. In a persuasive essay, Reiss argues that there is no justification for withholding vigorous support from a geriatric patient once a decision to proceed with surgery is made.[4]

Finally, the patient developed postoperative complications to which the elderly are particularly susceptible, one of which, the pneumonia, was fatal

The elderly are different than younger adults. As emphasized in my recent review, they are, like pediatric patients, not just adults of shorter stature.[5] Geriatric patients succumb to different diseases. Perhaps most importantly, they have different expectations and values concerning the quality and quantity of their remaining lives.

The rate of surgical procedures in adults increases with chronological age. About 136 procedures per 100,000 population are performed in people age 45 to 64, but this increases to 190 procedures per 100,000 in patients 65 years and older.[6] As the mean age of the population increases, more of the surgery performed in this country will be done on the aged. Just as in younger patients, however, the risks of surgery can be minimized by the improvement of procedure-related and patient-related risk factors which I will briefly discuss.[7]

I will first present an overview of some aspects of the decision making process which brings an elderly patient to the operating room.

Surgical Decisions in the Geriatric Patient

As late as 1981, it was recommended that surgery in geriatric patients be avoided until "all non-surgical management modalities have been exhausted."[8] More appropriately, a decision to operate on even the oldest patient presents a decision that the benefits of surgery outweigh the possible risks. Communicating with the patient and allowing the decision to be to the greatest extent possible the informed patient's are often very demanding tasks.

Physicians often underestimate remaining life span in their elderly patients, and may not even consider surgery. It is important to note that the average 70 year old man will live to be 81 years old, and his 70 year old wife will live to be 84.[9]

The mortality rate from surgery for nearly every surgical procedure is higher in geriatric patients.[10] Yet there is good evidence that for even the most difficult of procedures this rate is declining.[2,11]

With the exception of cancer and vascular surgery, geriatric patients who survive surgery have a near normal quantity of remaining life.[12,13] Quality of remaining life after geriatric surgery is not yet as well studied, except in cardiac surgery: New York Heart Association functional class improves for geriatric patients after surgery.[14,15]

Procedure-Specific Considerations in Geriatric Surgery

Sometimes the risk associated with the surgical procedure itself is the dominant consideration in the surgical decision. Particularly common surgical disease in the elderly include cataracts, prostate pathology, osteoporosis, biliary disease, and solid tumors.

As is the case for younger adults, any surgical procedure performed in the thorax or the peritoneal cavity markedly increases the mortality risk for the geriatric patient.[16] Intermediate risk procedures include vascular and hip procedures. Relatively low risk procedures include prostate surgery and mastectomy.

Cataract surgery in the geriatric patient. Cataract surgery under local anesthesia is extraordinarily safe. Only one death occurred in 20,000 procedures under local anesthesia.[17] In a series of 258 ophthalmology patients who had preoperative evaluation by a general internist, only three life-threatening perioperative complications occurred.[18] Although these complications were not predicted, other important medical problems were detected by the preoperative evaluation.

Prostate surgery in the geriatric patient. Prostate surgery, especially transurethral surgery, is relatively safe, even for patients with cardiac disease. In 1938, transurethral resection of the prostate was associated with a mortality of 1.6%.[19]

Despite the fact that cardiovascular complications are the principle causes of mortality, prostate surgery should not be necessarily denied patients with cardiovascular disease, even those with recent myocardial infarction. There was only one death in 23 patients operated on within six months of myocardial infarction.[20] In the same series, the authors suggested delaying prostate surgery for two or three months if urinary outflow obstruction occurred after previous "major surgery." Although a reasonable suggestion, its validity is not able to be substantiated by the data presented.

Pulmonary embolism may be minimized by early postoperative ambulation. Sudden dilution of blood by bladder irrigation may cause hyponaturemia and hypotension.

Orthopedic surgery in the geriatric patient. Complications of osteoporosis account for most of the orthopedic surgery done, especially in the very old. In a

series of six centenarians, two procedures were performed for hip fractures.[22] For patients who were ambulatory before hip fracture, surgery is usually appropriate. However, debilitated patients who managed without surgery survive longer with fewer complications than those who have surgery.[23] Hip-fracture-procedure-related mortality may be as high as 25%,[24] but after six months the hip fracture patient survives about as long as his peers.[25] Other important points with respect to hip fracture in geriatric patients are that delay in surgical intervention increases mortality and prophylaxis against deep vein thrombophlebitis should be used,[26] constipation of heroic proportions is common postoperatively, and blood transfusions should be given with restraint postoperatively, consistent with hemodynamic stability. This is to minimize post-transfusion hepatitis, a problem that can cause major post-discharge problems for the frail elderly patient.

Laminectomy surgery has a mortality of 1% or less, and may be dramatically palliative in geriatric patients with chronic root compression symptoms or acquired spinal stenosis from osteoarthritis.[27]

Biliary surgery in the geriatric patient. Because gallstones and infected bile are more common in old people, biliary surgery is also common and often complicated.[28] Most patients with suppurative cholangitis are elderly, and empyema, gangrene, and perforation complicate acute cholecystitis more frequently in the elderly.[29] One third of emergency abdominal procedures in patients above 70 are for biliary disease.[30] All biliary surgery in patients over 70 should be done with antibiotic prophylaxis against common biliary pathogens.[31]

Gastrointestinal surgery in the geriatric patient. Upper gastrointestinal bleeding is associated with a higher mortality in geriatric patients, especially if the bleeding is from a gastric ulcer.[32] Earlier operative intervention in the geriatric patient may be appropriate.

Atypical symptoms and a more rapid progression to perforation make appendicitis more threatening to the elderly patient.[3] Appendicitis should be suspected in aged patients with acute abdominal symptoms, and surgery should not be delayed for protracted "stabilization" of the patient.

Acute mesenteric ischemia, either from thromboembolism (occlusive) or low flow rates (non-occlusive or vaso-spastic) is another disease to which the elderly are susceptible and in which delay in intervention is usual. An aggressive approach combining angiography and papaverine infusion with surgery as necessary has been advocated,[33] and seems reasonable in selected high risk patients who develop severe abdominal pain out of proportion to physical signs.

Diverticular disease is more commonly symptomatic in the elderly; surgery is performed for macroperforation, fistula formation, and obstruction.[29] Percutaneous drainage of intraabdominal abscess may be an attractive alternative to surgery in the elderly.[24]

Colonic volvulus, especially of the sigmoid colon, is a condition almost unique to the geriatric age group. It can present either with acute symptoms of complete obstruction or with more chronic symptoms. It may sometimes be managed conservatively, employing colonoscopy for decompression.[35]

The association in geriatric patients of calcific aortic stenosis and recurrent gastrointestinal bleeding from angiodysplasia (arteriovenous malformation or ectasia) is well established. Remarkably, there is anecdotal evidence that the bleeding may stop with aortic valve replacement.[36]

Other considerations. Regional anesthesia and spinal anesthesia can be effective techniques for the elderly, although lumbar puncture may be technically more difficult.[37] No study exists that documents superiority of any particular anesthetic technique in elderly patients, but spinal anesthesia may be associated with less postoperative disorientation[38] and less myocardial depression,[39] an important consideration in patients with precarious left ventricular pump function.

Organ Considerations in Geriatric Surgery

Generally, there is age-related physiological decline which affects all organ systems.[40] The perioperative significance of this decline depends on the organ system involved.

The diagnostic road traveled to surgery may further compromise the function of the geriatric patient's major organ systems. For example, nephrology or intravascular volume depletion may occur following angiography.

Since the major causes of death in the elderly surgical patient are cardiopulmonary and infections, the states of the heart, lungs, and immunological systems mainly determine the likelihood of survival.[41] Stroke causes some postoperative deaths in geriatric patients. For this reason, and because postoperative delirium can interfere with postoperative therapy and cause self-inflicted injury, the preoperative state of the patient's central nervous and cerebrovascular system is also important.

The preoperative history and physical examination will readily enable identification of high risk patients. Of use is the American Society of Anesthesiology (ASA) Classification System. Adopted in 1974 by the House of Delegates of the ASA, the system classifies patients according to the following categories:

Class 1 - A normally healthy patient.

Class 2 - A patient with mild systemic disease.

Class 3 - A patient with severe systemic disease that is not incapacitating.

Class 4 - A patient with incapacitating systemic disease that is a constant threat to life.

Class 5 - A moribund patient who is not expected to

survive for 24 hours with or without operation.

Emergency cases are designated by the addition of "E" to the class number. Patients over 80 years of age, even if healthy, are assigned to class 2.[42]

In a series of surgical patients over age 80, fewer than 1% of Class 2 patients died, while 25% of Class 4 patients died. Active patients, defined as those who "normally left their home as a result of their own efforts at least twice weekly," were found to have a dramatically decreased surgical mortality in a study by Seymour, et al (Fig. 1).[43]

Cardiovascular considerations in the geriatric patient. Cardiac complications are the most common causes of death in geriatric surgical patients, particularly in those undergoing cardiac or vascular procedures.[14,44] Although age itself is an independent risk factor for cardiac complications in general and bypass surgery,[14,45] and has been assigned a value in a useful cardiac index developed by Goldman, et al,[45] a dynamic evaluation of cardiac reserve may offer additional help in identifying high risk patients.

In 1971 and again in 1980, DelGuercio and colleagues endorsed Swan-Ganz catheterization in geriatric patients undergoing elective "major" surgery.[46,47] Despite the risks of this invasive technique, they had no complications. They were able to identify a subset of patients with extremely high surgical mortality due to "incorrigible" ventricular dysfunction, which seemed to be defined as an inability to drop pulmonary capillary wedge pressure below 15 mm Hg. They also found that patients with "normal" physiology did well at surgery.

I believe it is reasonable to conclude that Swan-Ganz catheterization identifies high risk patients, and, because of its utility in postoperative management, should be strongly considered in geriatric patients in ASA Class 3 or higher, particularly if they have high cardiac risk by Goldman criteria,[45] and are undergoing abdominal, thoracic, or vascular surgery.

Gerson, et al, found that the simple inability to exercise on a bicycle for two minutes to a heart rate of greater than 99 beats per minute results in an 11-fold increase in cardiac complication rate in elderly patients (mean age 72.9) undergoing elective abdominal and thoracic surgery.[48] Exercise capacity was "generally more limited by impaired joint mobility, dementia or muscle weakness than by leg claudication or exertional angina," and probably is the laboratory equivalent of Seymour's activity index (Fig. 1).

An "exercise-equivalent" thallium scan using intravenous dipyridamole has been found to be useful in predicting cardiac complications in patients (mean age

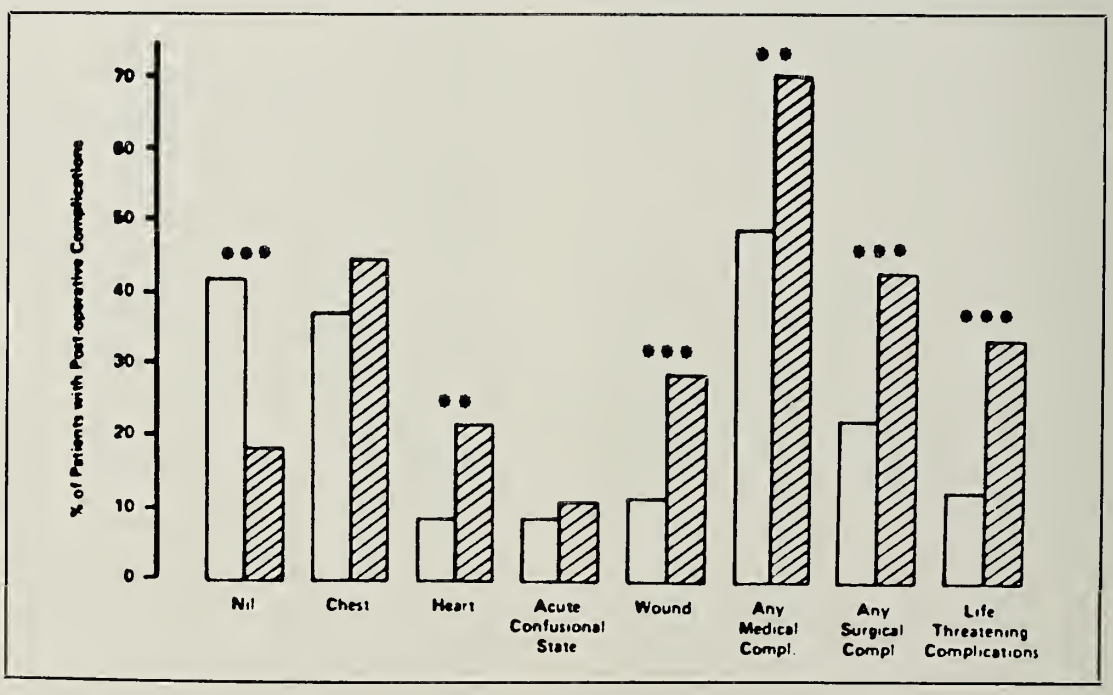

FIGURE 1

Pre-operative activity level and post operative complications. ☐ = Active patient (n = 189); ▨ = inactive patient (n = 64). *p < 0.05, **p < 0.01, ***p < 0.001. Reprinted from Seymour, et al, by permission.[43] Active patients are defined as those who "normally left their homes as a result of their own efforts at least twice weekly."

63) undergoing surgery for peripheral vascular disease, a population at high risk for associated coronary artery disease.[49] This technique may be applicable to the evaluation of geriatric patients in general, but awaits trial.

Calcific aortic stenosis is a common geriatric disease, and is a Goldman cardiac risk factor.[45] Differentiating benign systolic murmurs from significant aortic stenosis may be difficult. Significant aortic stenosis may have a prolonged murmur, extending near the pulmonic second heart sound and frequently obscuring the aortic second heart sound, left ventricular hypertrophy on EKG, calcification in the aortic valve on chest film, or the finding of a "palpable lag time" between apex impulse and cardiac impulse.[50] Echocardiography may suggest left ventricular hypertrophy and a deformed aortic valve. Patients with significant aortic stenosis should receive antibiotic prophylaxis, and care should be taken to ensure adequate left ventricular filling pressure, with or without Swan-Ganz catheterization.[51]

Generally, patients with asymptomatic bifascicular block do not need pacemakers for surgery.[51] Patients who have ventricular demand pacemakers may have problems with electrocautery, as reported in a transurethral prostate resection.[52] This should not be a problem if the pacer is maintained in a fixed mode during surgery.[53]

Old patient's mesenteric vasculature is a source of cardiovascular risk. In the series of patients over age 80, six of the seven deaths that occurred within 48 hours of surgery were from mesenteric infarction.[42] Conceivably, strict attention to optimal fluid and blood pressure maintenance using Swan-Ganz catheterization would minimize this complication in high risk patients.

Pulmonary considerations in the geriatric patient. The physiologic changes of aging and the accumulated risk for acquired pulmonary disease place the geriatric patient at especially high risk of pulmonary complications, especially pneumonia.[54] As in the younger patient, pneumonia follows atelectasis, and is more likely to occur following abdominal or thoracic surgical procedures.

The perioperative preparation of patients to minimize pulmonary risk is essentially the same as that for younger patients. Preoperatively, bacterial bronchitis should be treated before elective surgery. Bronchospasm needs to be controlled. The geriatric patient would probably benefit from preoperative rehearsal of the equipment and procedures used in postoperative respiratory care. Narcotics should be titrated to the point of appropriate pain relief without over-sedation. Old people should be mobilized as early and as fully as possible with caution.

Obesity is common in patients past mid-life,[55] and is associated with an increased risk of thromboembolism,[56] an important consideration for all surgery in geriatric patients.[56]

Immunologic considerations in the geriatric patient. The elderly are at higher risk for postoperative infections due to a number of factors. Probably the most important is the real but ill-defined decline in both cell and humoral-mediated immunity, which has been termed, immunosenescence.[57]

A common but often hidden problem in the elderly is malnutrition.[58] This predisposes the patient to infectious complications because of immunocompromise, and is detectable by the finding of below-normal levels of serum albumin or transferrin. Nutritional supplementation before elective surgical situations would be expected to decrease operative risk.

Attention to antibiotic prophylaxis is important in the elderly, particularly in procedures involving the urinary and biliary tracts. Pathogenic organism colonization is common in these sites, and is often asymptomatic.[59]

Central nervous system considerations. Cognitive and psychiatric decline are common in geriatric patients after surgery. Postoperative delirium affects 10 to 15% of patients, and pre-existing brain injury from dementia or stroke pre-disposes the patient to this complication.[60] Delirium can be caused or worsened by reversible factors including covert infection, drug toxicity, and metabolic derangements, often dilutional hyponatremia.

Encouraging the family to visit at regular times and to orient the patient to time and situation when they visit, making sure the patient's glasses and hearing aid are on and not sitting in a drawer, and supplementing the hospital staff with private duty aid when financially possible, may shorten the period of risky postoperative delirium. Small doses of haloperidol in the non-Parkinson patient are useful. Restraints must be used with caution, as they sometimes agitate the patient more than they help.[61]

Parkinson's disease, a common affliction of the geriatric population, causes perioperative problems mainly because of associated rigidity. Postoperative mobilization and respiratory therapy are often difficult in Parkinson patients, and contribute to an increased pulmonary risk. Most patients, however, tolerate anesthesia and a short drug holiday very well, but l-dopa products should be taken right up to the time of anesthesia and restarted as soon postoperatively as possible.

An asymptomatic bruit from carotid stenosis is a marker of associated coronary artery disease,[62] and may indicate a greater risk of cardiac complication. Preoperative evaluation of the carotid circulation is generally unnecessary, however.

Elderly patients with a history of stroke, especially

recent stroke, are at some risk of worsening their previous deficit or of having a new insult. Careful preoperative neurological examination is required in order to detect any significant postoperative change.

Orthostatic hypotension may be particularly evident in the geriatric surgical patient, but should not prevent cautious efforts at early postoperative ambulation.[63]

Summary

The elderly, because of their increasing numbers and their more frequent need for surgery, represent an ever increasing proportion of surgical patients.

The case of an elderly patient who required surgery for an acute abdomen has been presented, and emphasizes that the frail elderly are different from younger adults. Procedure-related and patient-related risk factors specific for the geriatric patient have been presented.

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RENAL FUNCTION AND DISEASE IN THE ELDERLY

Laurence H. Beck, M.D.

Introduction

Narrowed functional reserve, the hallmark of the alteration in physiology in aging, is nowhere better demonstrated than in the kidneys of elderly individuals. Virtually all functions of the kidney become less flexible, less able to respond to stress. Despite these constraints, aging kidneys are able to maintain body fluid and solute homeostasis for most individuals through eight or nine decades of life. However, any added stress, be it physiologic, pharmacologic, or pathologic, can exceed the narrowed limits of homeostasis by the aged but otherwise normal kidneys, and can result in striking abnormalities of fluid and electrolyte metabolism.

This paper will review the changes in renal morphology and function that occur with normal aging, discuss the occurrences and prevention of several common renal-electrolyte syndromes in the elderly, and briefly consider some diseases of the kidney that occur with unusual frequency in older individuals.

Changes in Morphology

During normal aging, the adult kidneys gradually lose mass, shrinking from 250 grams at age 30, to 180 grams by age 90.[1] This decrease in renal mass is the result of the loss of as many as 30-50% of the glomeruli, particularly those in the outer cortex, and a somewhat less extensive loss of tubules. In addition, there is replacement of some of the interstitial tissue with fibroids.

The clinical implications of this change in renal size and mass are minimal. The physician needs to be aware of these changes when interpreting imaging studies of the kidneys in the elderly and, should renal biopsy become necessary, the target is smaller than in the younger patient.

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Changes in Renal Function with Aging

Much more important in terms of clinical consequences are the changes in renal function that occur with normal aging. These changes, which involve the glomerular filtration rate, salt and water conservation and excretion, potassium homeostasis, and acid excretion, are of a magnitude that does not cause clinical problems under normal circumstances. However, because of the decreased elasticity of the renal system, they can become important and occasionally life-threatening when some other stress shifts the balance of homeostasis.

Glomerular Filtration Rate

It was recognized many years ago that glomerular filtration rate, measured either by the creatinine clearance or by a more specific method such as inulin clearance, is lower in healthy elderly individuals compared to their younger counterparts. Cross-sectional studies, done in the mid-1970s by Rowe et al, characterized the magnitude of this decline, estimating it at about 1 ml/min/year.[2] More recently, the Baltimore Longitudinal Study of Aging has in large part corroborated this decline in glomerular filtration rate (GFR) in healthy ambulatory individuals over periods of follow-up as long as 20 years.[3] The average decline in GFR in this ongoing longitudinal study was 0.8 ml/min/year. Of great interest, however, was the fact that as many as 30% of these healthy aging individuals had no fall

whatsoever in their GFR over the period of observation. The reason for preservation of function in some aging persons and the relentless fall in others is unknown. Recently, Brenner and his associates have suggested that the progressive slow fall that occurs in GFR in healthy individuals of Western society is secondary to glomerular sclerosis induced by our chronically high protein diet.[4,5] Although there is good experimental evidence in animals that this may be the case, there is no confirming support in humans.[6]

Despite the fall in GFR rate with age, the serum creatinine concentration remains unchanged, the normal limits for a 90 year old being the same as for a 30 year old. The reason for this seeming paradox is that creatinine production, which is a reflection of total muscle mass, decreases with age at about the same rate as does the GFR. Although the parallel fall in muscle mass and in GFR is coincidental, the serum creatinine concentration (which reflects the ratio between creatinine production and GFR) remains constant in most normal individuals.

Hidden within the serum creatinine concentration, therefore, and of great importance to clinical management, is that a "normal" serum creatinine concentration in a 90 year old usually implies a GFR that is only one half the GFR of a 30 year old with the same serum creatinine concentration. This is particularly important to remember when prescribing drugs that are renally excreted or that are potentially nephrotoxic.

Water Homeostasis

It is well recognized that elderly individuals are unusually prone to dehydration and resultant hypernatremia.[7] This propensity results from changes in body composition, in central nervous system function, and in alterations of kidney function.

The elderly progressively lose lean body mass and accumulate fat, even in non-Western societies, so that the percentage of body weight that is made up of water falls from about 60% in a 30 year old man to 50% or less by the time he is 75 or 80 years old. Although this change alone is harmless from the standpoint of body water economy, any given water loss will result in a proportionately larger rise in plasma sodium concentration and osmolality than it will in a younger person.

The thirst mechanism is impaired in most healthy individuals in their 70s and beyond. Normally, any loss of body water that is sufficient to raise body fluid osmolality more than about 1% results in thirst and water-seeking behavior which persists until the dehydration has been corrected. However, it has been shown repeatedly that thirst is blunted or absent entirely from otherwise normal elderly individuals after a degree of dehydration that produces intense thirst in younger people.[8,9]

On the other hand, the hypothalamic-pituitary response to dehydration in terms of antidiuretic hormone (ADH) release is not impaired and may even be exaggerated compared to younger individuals.[10] Circulating plasma ADH concentrations are higher at basal conditions and under conditions of hyperosmolality in the elderly. Despite these normal to high values, the kidney's response to dehydration, the formation of a concentrated urine is impaired. The maximal urinary osmolality which regularly exceeds 1000 mOsm/kg in younger individuals during dehydration, is progressively impaired with aging, so that maximal urinary osmolality of only 600-800 mOsm/kg is not unusual in normal individuals in their 70s and 80s. In other words, despite normal levels of ADH there is relative failure to conserve water by the kidney during dehydration. This change represents a mild form of nephrogenic diabetes insipidius. Whether the renal tubular cells or their receptors are abnormal, or whether the failure to respond normally to ADH is due to decreased renal medullary hypertonicity is uncertain.

The result of these defects is a tendency toward dehydration, particularly when older individuals are under the stress of another illness and either cannot take in oral fluids, as with vomiting or gastroenteritis, or do not have access to water, such as in stroke, coma, or depressed mental state. The ongoing insensible loss of water from skin and lungs, coupled with hypotonic fluid loss from the gastrointestinal tract, and ineffective water conservation by the kidney, can lead to dramatic dehydration, evidenced clinically by skin tenting and decreased mental status, and by the laboratory finding of severe hypernatremia.

Sodium Homeostasis

When faced with a decreased sodium intake and superimposed salt loss from diarrhea, healthy young individuals rapidly lower their urinary excretion of sodium by increasing their tubular reabsorption of filtered sodium. This response, which is mediated largely through renin, angiotensin, and aldosterone, limits the magnitude of the body's sodium loss and thereby helps protect against extracellular volume depletion. On the other hand, the elderly individual has a much slower response to volume depletion or decreased sodium intake so that inappropriate urinary sodium excretion may continue in the urine for several days despite increasing hypovolemia. This relative homeostatic failure, similar to that observed in mild chronic renal failure, appears due in part to decreased renal renin release (and thereby decreased angiotensin and aldosterone), and in part due to decreased renal tubular responsiveness to aldosterone.[11]

This combination of impaired water and sodium homeostasis under stress, characteristic of the aging individual, frequently results in dramatic elevations of the BUN, and occasionally of the serum creatinine

concentration, due to poor perfusion of the already compromised aging kidney. It should be recognized, however, that this form of acute renal insufficiency should be completely and rapidly reversible with appropriate replacement of the underlying salt and water deficit.

Other Renal Tubular Functions

Renal excretion of a potassium load and hydrogen ion (acid) load is decreased in rate and capacity in healthy older individuals compared to younger.[12] The precise mechanisms for these impairments are not well understood, although both may be partly secondary to the renin secretory defect noted above. Under normal circumstances, potassium and acid-base homeostasis is preserved, even in very old individuals. However, if there is an unusual load of either exogenous or endogenous potassium, or of acid production (as often occurs in serious acute illnesses), the narrowed homeostatic limits may be surpassed, with resultant hyperkalemia and metabolic acidosis. Clinical advice arising from these changes is to be very cautious with potassium prescription in the elderly, particularly when used parenterally, to anticipate metabolic acidosis during acute severe illness and, if appropriate, to counteract the acidosis with exogenous base (sodium bicarbonate).

Acute Renal Failure

Age appears to be a risk factor for several types of acute renal failure. In part, this is due to the fact that the normal glomerular filtration rate (GFR) of the elderly patient is low, and it takes less of an insult to result in a dramatic rise in BUN and creatinine. In addition, the limited defense against salt and water loss makes acute prerenal failure particularly common. It has been suggested that the aging kidney is more susceptible to a number of insults, such as aminoglycoside nephrotoxicity, radiocontrast dye-induced acute renal failure, and postsurgical acute tubular necrosis. Although in the clinical studies available it is difficult to isolate age *per se* as an independent risk factor, there is a general impression among clinicians that the older individual is at increased risk.[13] Furthermore, after acute renal failure the recovery of renal function is often slow and incomplete in older individuals, with the serum creatinine not returning to baseline even after several weeks or months.[14]

The diagnostic evaluation of acute renal failure in the elderly should not differ from that in the younger individual, except that radiocontrast dye should rarely, if ever, be used. Renal ultrasound is adequate for anatomic definition. Furthermore, the higher prevalence of obstruction as a cause of acute renal failure in the elderly makes it incumbent to rule out that diagnosis early in every evaluation. Again, renal ultrasound is a sensitive diagnostic test for detecting upper tract dilatation consistent with obstructive uropathy.[15]

A cause of acute renal failure for which the elderly may be at unusually high risk is that caused by nonsteroidal antiinflammatory drugs (NSAIDs).[16] These drugs block prostaglandin synthesis within all organs, including the kidney. Renal prostaglandins are important in the intrarenal control and autoregulation of glomerular filtration rate (GFR), particularly in situations where there is decreased renal blood flow or low renal perfusion. Such conditions are common in older individuals, in part due to the intrinsic decrease in renal function with aging, but also with disease states associated with volume depletion, congestive failure, or other low-perfusion conditions. In such situations the use of NSAIDs often results in a rapid rise in BUN and serum creatinine concentration, sometimes accompanied by other metabolic abnormalities, especially hyperkalemia. Now that ibuprofin, the prototype NSAID, is available without prescription, it is expected that there will be an increased incidence of this type of acute renal failure.

Acute renal failure induced by NSAID should be rapidly reversible within two to three days after discontinuation of the drug. If renal function does not recover within this time period, the physician must look for some other cause of the renal insufficiency.

Because of these effects of NSAIDs, the physician should use them with caution in elderly patients, particularly those with any underlying renal dysfunction. If no acceptable substitute drugs are available, the physician should check the serum creatinine before, and three to four days after beginning NSAIDs, in order to recognize a toxic effect promptly.

Chronic Renal Disease in the Elderly

In general, the elderly exhibit the same range of diagnoses leading to chronic renal disease, glomerulonephritis, and nephrotic syndrome as do younger patients. Although the incidence may vary somewhat with age, in the individual patient presenting with one of these syndromes, the same differential diagnosis should be considered, with perhaps a couple of additions and associations recognized.

Atheroembolic renal disease is predominantly a condition of old age. It is characterized by acute or sub acute renal failure occurring in individuals with diffuse atherosclerosis. Most of these individuals have severe disease of the abdominal aorta, often with aortic aneurysm. The renal disease occurs when cholesterol crystals and other atheromatous material embolizes to the cortical arteries of the kidney with resulting ischemic necrosis. The condition can occur abruptly after aortography or aortic surgery in which renal failure is acute, or spontaneously and insidiously, resulting in progressive renal insufficiency over several weeks to months. There are few clinical clues to the latter syndrome except for evidence of atherosclerosis elsewhere, particularly in the lower extremities.

Nephrotic syndrome in the elderly individual can be secondary to lipoid nephrosis just as it can in the one year old, although the prevalence is obviously much lower. Similarly, other histologic diagnoses present themselves as well. There is evidence that onset of nephrotic syndrome in patients above the age of 55 should be considered a marker of an underlying malignancy. Although the original estimates of 20-30% were too high, the proportion of such individuals with an underlying cancer is high enough, probably about 10%, to warrant a search for the tumor.[17] It is uncommon for the associated malignancy to be truly hidden for long when nephrotic syndrome appears first.

Urinary tract obstruction is a common cause of acute and chronic renal insufficiency in the elderly and must always be considered. It is much more common in men, due to benign prostatic hypertrophy and prostatic cancer, although elderly women can develop bilateral ureteral obstruction due to advanced cervical carcinoma or to severe uterine prolapse.

The usual symptoms of bladder outlet obstruction of hesitancy, dribbling, frequency, and decreased force of stream are present in patients with benign prostatic hypertrophy. However, these symptoms may be entirely absent in prostatic cancer with obstruction of the ureters at the bladder trigone.

Because obstructive nephropathy is a potentially reversible cause of renal failure, and because it is often silent, the primary physician should always rule out obstruction when evaluating an elderly patient with acute or chronic renal failure. Intravenous urograms should not be used, due to the possibility of superimposed radiocontrast-induced acute renal failure. Instead, the renal ultrasound should be the initial diagnostic test.

Clinical Implications for Drug Therapy

Due to the fall in GFR rate with aging, it is particularly important to avoid superimposed nephrotoxicity. In addition, the physician must be particularly careful about the dosages of all drugs for which the kidneys represent the dominant clearance mechanism. Many drugs are cleared principally by glomerular filtration. Drugs such as aminoglycoside antibiotics or digoxin, and particularly those with significant dose-related toxicity, must be given in reduced doses to any individual with decreased GFR. As has been seen, the fall in GFR with aging is masked by the change in muscle mass and only the serum creatinine concentration is relied upon as an estimate of GFR. On the other hand, it is difficult and time consuming to carry out 24 hour urine clearances in elderly patients in order to calculate the precise creatinine clearance. Most clinicians have become dependent upon formulae for estimating GFR, which depend on the serum creatinine concentration. The most widely used of these takes into account the change in GFR with age:[18]

$$\text{creatinine clearance} = \frac{(140 - \text{age}) \times \text{body weight (in kg)}}{72 \times \text{serum creatinine (mg/dl)}}$$

Unfortunately, this formula performs poorly in the seventh, eighth, and ninth decades, as it estimates a higher GFR than actually exists.[19] Most drug-dosing nomograms, which account for age and renal function, also use this formula as a basis for their recommendations. The clinician needs to recognize this systematic error in GFR estimation, to dose with extreme caution in the very old patient, and to rely on serum drug concentrations for tailoring drug dosage to the individual patient.

Conclusion

Caring for the elderly patient with renal disease can be challenging. The goals should be similar to the goals of all geriatric medicine: maintenance of function and avoidance of excess disability from disease. Most elderly patients can remain surprisingly functional despite the morbidity of one or more chronic diseases, and despite the narrowed physiologic reserve previously discussed. By remembering the principles reviewed in this article, the primary physician can play an important role in helping the elderly patient to maintain that level of function.

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PSYCHIATRY AND THE ELDERLY: DIAGNOSIS, TREATMENT, AND MEDICAL/ETHICAL DILEMMAS

David E. Raskin, M.D.

Introduction

The following psychiatric disorders are most common in elderly persons: disorders of cognitive function including delirium and dementias; affective disorders of all kinds ranging from mild, situational depressions to agitated depressions with delusions (psychotic depressions); and generalized anxiety disorders including phobic and obsessional components.

To make things even more complicated, these disorders can occur in various combinations in a single patient.

Delirium

Delirium represents a state in which the cardinal symptoms include attention/concentration impairments, and disorganized thinking.[1] Other symptoms include reduced consciousness, perceptual disturbances, disruption of sleep cycle, disorientation, and memory disturbance. The patient's conversation will wander off the track or become derailed. The patient will have difficulty repeating digits and, in more formal psychological tests such as digit span or digit symbol, performance will be less than optimal. When interviewing at the bedside, the use of unstructured questions, the presence of other stimuli (such as the television set being on or the patient talking to a nurse or someone in the next bed) will all cause a decrement in the patient's interview behavior.

A primary issue in patients who develop sudden delirium is to perform a careful assessment of occult medical disease such as urinary tract infection, or the contribution of physician-prescribed medications such as tricyclic antidepressants which cause anticholinergic induced delirium. It should be noted, however, that there remains a small core of patients with delirium in whom the etiology is unknown. Moreover, many patients transferred either from nursing homes or their residence to the hospital will develop a temporary, brief delirium while adapting to their new surroundings. Sometimes this is a clue to the presence of a hidden dementia.

Dementia

Dementia involves memory impairment and associated symptoms of impairment in abstract thinking, impaired judgment, disorders of higher cortical function, and personality change.[2-4]

The most common form is primary degenerative dementia, or Alzheimer's disease. The second most common is multiinfarct dementia, most often associated with hypertension. There are patients who have mixed states. A small number have reversible dementing illness, so the clinician must look for such entities as pernicious anemia, thyroid disease, or brain tumor. The most common form of reversible dementia is associated with depression. These patients characteristically present by themselves to the physician's office and do not deny their illness but, in fact, embellish it. They have highly variable performances on both clinical and psychological assessment.

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One caveat is necessary. It now appears that in early dementia there may be an accompanying depression, and every clinician working in this field has made the mistake of diagnosing depression in a patient who goes on to a more frank dementia. As long as the clinician remembers that dementia progresses over time, a tentative diagnosis can be made and then confirmed with the passage of time. Dementia is a global phenomenon, affecting intellectual functioning and social skills. Unlike delirium, dementia does not usually affect concentration or attention unless the disease is advanced. The demented patient who is not medically ill or affected by a superimposed delirium will be able to do digits or psychological tests which tap into attention/concentration. Because the patient does not in the initial stages of dementia have attention or concentration deficits, there are a number of patients who can sneak by in an interview by avoiding questions. Clinicians should look for denial of illness, avoidance of questions, and a tendency to use either anger or humor to push the examiner aside when an attempt is made to evaluate intellectual functioning.

At the present time, there is no biological treatment for dementia. The current treatment is the use of certain environments which appear to tremendously reduce demented behavior. These environments require a consistency of nursing staff and physical environment. In our experience at the Kutz Home, such a program has dramatically reduced acting out by demented patients. In patients who develop secondary symptoms of delusions or hallucinations, antipsychotic medications given carefully in low doses are indicated.[5] We have little idea of what helps in the aggressive demented patient but many medications have been tried, including trazodone (Desyrel, Mead Johnson), amitriptyline (Elavil, Merck Sharp & Dohme), lithium, and in the end when these more specific forms of treatment fail, antipsychotic medication. I appeal to physicians and caretakers to try to work out a consistent environment for demented patients since this still appears to be the simplest way to change disruptive behavior. This means it is not helpful to send non-nursing home individuals south for the winter, or to send them from one living situation to the next. To expose the demented patient to new and incomprehensible experiences is to abet dysfunction.

Medical/Legal Issues in Dementia

Several life sustaining technologies are used in demented patients.[6] These include CPR, mechanical ventilation, nutritional support and hydration, antibiotics, and renal dialysis. It is not appropriate for clinical decision making to lump all elderly people who require such life sustaining technologies together. Distinctions can be made between critically ill, chronically ill, severely disabled, and terminally ill (ie, expected to die within six months). In addition, the elderly vary in their degree of decision making capacity. "Decision making capacity" should be used instead of the term "competency," which should be restricted to a legal determination about decision making status. With issues about the rationing of such technologies, the high cost of dying, and quantity- and quality-of-life decisions, several medical/legal and ethical issues become relevant in the care of demented patients. In practice, diffeent treatment modalities for a single technology can involve different decision making. For example, nasogastric tube placement is often accomplished without the patient's consent. Full consent is usually required for gastrostomy tube placement or a catheter for total parenteral nutrition. At present, the most controversial life sustaining technology is clearly nutritional support. The debate centers around the question of whether tube or intravenous feeding and hydration are food and water or medical treatment. Although lower court cases tended to support the concept of nutritional support as food and water, more recent higher court decisions have gone in the other direction and have permitted the withholding of nutritional support.[7] The legal balancing involved in all decisions around these life sustaining technologies is a balance between the common law right of self determination (Union Pacific Railway Company v. Botsford and Schloendroff v. New York Hospital 1914, and Nathanson v. Kline, 1960), along with the constitutional right to privacy; and societal interests that limit the patient's right to refuse, including concerns about the preservation of human life, protection of third parties, prevention of suicide, and the protection of the ethical integrity of the medical profession.

Although elderly patients capable of decision making should have the clear legal right to refuse, lack of agreed-upon criteria for decision making capacity and the widespread societal myth that the elderly are senile may interfere with elderly patients exercising this right. For patients who become incapable of decision making, delegation of durable power of attorney or the execution of a living will represent two ways of providing for that point in time. For incapable elderly who have not used such procedures, the courts may appoint surrogate decision makers or use informal surrogate decision making, or in some states family consent laws exist. In most states, there is no legal authority for family members to make decisions on behalf of their elderly relatives, even though this is a common and widely accepted practice.

In summary, the following guidelines may be considered sound practice: the attending physician who concludes there is no reasonable hope a patient will return to a cognitive sapient state should obtain a second opinion before discontinuing life support systems; before any decision is made to discontinue life support systems, the patient's family and/or guardian must agree

with that decision; and if there is a disagreement among family members, life support systems should be discontinued only by court order.

The interaction between developments in clinical care of demented patients and medical/legal decision making promises to be an important one in the future.

Depression

Depression in the elderly presents with the same fundamental symptoms as in middle aged adults.[8] The patient exhibits sadness, hopelessness, helplessness, and occasionally anxiety or panic. Interference with biological functioning including sleep, appetite, and energy occur along with loss of libido. Social relationships and interests atrophy. As stated earlier, depressed patients can often develop psychotic symptoms, including delusions of being sinful or impoverished. With the seriously ill depressed patient with severe biological signs, and particularly in the presence of delusions, electroconvulsive therapy is the treatment of choice due to its immediate effectiveness and its low side effect profile. If the patient has a milder form of depression, tricyclic antidepressants particularly the secondary amines such as nortriptyline (Pamelor, Sandoz) or desipramine (Norpramin, Merrell Dow) appear to be safer medications to use in the elderly. MAO inhibitors can often be effective, particularly in patients with panic states associated with depression, but orthostatic hypotension is a side effect which needs to be carefully considered. The dietary proscriptions involved in taking these medications become real considerations in noncompliant patients. Another class of agents which may be of help are the psychostimulants, which at low doses work rapidly for anergic depressed elderly patients without appetite loss or tolerance.

Medical/Legal Issues in Depression

Case Study

J.R., an 80 year old woman, has been reliably diagnosed as being depressed. Her depression is serious with sleep disorder, weight loss, and feelings of hopelessness. She refuses electroconvulsive therapy and antidepressants. Her reasons are, "Those treatments cannot help me." When questioned further, she states, "If help were available, I'd take the treatment, but no treatment will help." The forensic psychiatrist is asked to see her and formulate an opinion.

Forensic Psychiatrist Assessment

The risk-benefit ratio is clearly tipped towards benefit in this medically healthy 80 year old woman. Of course, adults capable of decision making have the right to refuse. Is she capable? She is not, since her depressive disorder has markedly interfered with her capacity to appreciate the risks, benefits, and consequences of the treatments offered versus no treatment. In the situation of a non-senile, actively protesting but a person incapable of decision making, depressed but otherwise healthy, the forensic psychiatrist recommends that the family obtain a court order for treatment. If the family refuses, should the institution initiate legal proceedings? What is the physician's ethical duty in such a situation?

Generalized Anxiety States

Generalized anxiety is a constant condition in the elderly who live alone and suffer chronic illness and repetitive fears of death. In the treatment of chronic anxiety, a careful history for drug and alcohol abuse is critical, particularly since these abuse patterns appear to be increasing in the older population. In addition, the clinician has to be careful about the use of antianxiety medications; in my experience, elderly patients tend to overuse and abuse these medications. It behooves the clinician to distinguish chronic anxiety disorders in the elderly from depression, which can present with patterns of anxiety but almost always is accompanied by biological signs of depression. In addition to benzodiazapines, which are the standard treatment for anxiety, we now have buspirone, which is effective in the treatment of anxiety. Patients need to be told that this medication has a lag time before onset but its advantages of nonaddiction and nonsedation make it a medicine to definitely be tried in the anxious elderly patient.

Psychotherapy

Psychotherapy of a supportive nature by someone experienced in nuances of patient/therapist relationships can be helpful in elderly patients suffering from anxiety and depression. In addition, group therapy is already a powerful tool in nursing homes and potentially also in the community. The Department of Psychiatry at The Medical Center of Delaware is currently using a group therapist to investigate this in a mixed group of elderly nursing home patients.

Summary

Delirium, dementia, depression, and anxiety are psychiatric conditions common to geriatric patients. Psychopharmacology, psychotherapy, and environmental manipulation are the treatments available for these diagnoses.

Medical/legal concerns and ethical questions regarding capacity for decision making and life support systems abound, and physicians need to be aware of them in providing care to the elderly.

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THYROID DISORDERS IN THE ELDERLY

William L. Jaffee, M.D.

Introduction

Thyroid disorders are common, and the incidence of many forms of thyroid disease increases with age. Although there are no fixed changes in thyroid function with aging, chronic disease, poor nutrition, and the use of medication such as beta-blockers result in impaired conversion of T4 to T3. Many of these conditions also result in decreased levels of thyroxine-binding globulin. Consequently, an increased incidence in the elderly of euthyroid sick syndrome might be expected, as well as euthyroid hyperthyroxinemia.[1]

I have specialized in endocrinology for more than ten years, and have been medical director for a large geriatric community for more than six. My experience with the clinical manifestations of both hypothyroidism and hyperthyroidism in the elderly leads me to the conclusion that no clinician can reliably detect either of these disorders by clinical criteria alone. Classical findings of myxedema such as thick, dry skin and bradykinesia are common in elderly patients with normal thyroid function. Consequently, the clinician may assume that findings actually due to hypothyroidism are merely age related. Likewise, hyperthyroidism may have few manifestations in the elderly.[2] The clinical syndrome of apathetic thyrotoxicosis may be related to impaired conversion of T4 to T3, or perhaps may be a manifestation of autonomic nervous system dysfunction with impaired sympathomimetic manifestations by hyperthyroidism.

As the physical manifestations of altered thyroid function are less obvious in elderly patients, they should have thyroid functions checked every few years. I personally obtain a total T4 and T3 uptake, while other clinicians prefer to obtain only a free T4, which is equally effective. In patients in whom there is a question of hypothyroidism, a TSH should also be done. When hyperthyroidism needs to be excluded, a triiodothyronine should also be measured. In patients where a discrimination between euthyroid hyperthyroxinemia and T4 toxicosis is necessary, TRH stimulation testing is the study of choice.[3]

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Hyperthyroidism

New onset hyperthyroidism in the elderly is relatively uncommon although the absolute incidence in this population has not been reliably reported. Etiology of hyperthyroidism is most commonly Graves' Disease, but toxic adenomas and toxic multinodular goiters are relatively more common than in younger age groups. These etiologic diagnoses may be supported by thyroid scan showing nodular disease, as well as radioiodine uptake to evaluate the rate of iodine turnover. Most authorities agree that hyperthyroid patients over age 40 should ultimately be treated with radioiodine rather than surgery. However, transient exacerbation of hyperthyroidism may occur after radioiodine therapy,[4] and cases of thyroid storm in this setting have been reported. Therefore, in patients with symptomatic hyperthyroidism who are elderly or otherwise compromised, it is appropriate to pretreat with antithyroid drugs to deplete the gland of preformed thyroid hormone. After normal thyroid hormone levels are achieved, antithyroid drugs may be withdrawn, and radioiodine therapy given with a greater degree of safety. In general, larger doses of radioiodine are needed for nodular disease than for Graves' Disease. Other than the induction of hypothyroidism, there are no adverse long term consequences of radioiodine treatment.

Therapy with beta-blockers may be used to control sympathomimetic symptoms of hyperthyroidism,

which are less prominent in elderly thyrotoxic patients than in younger people. Also, elderly patients may also have congestive heart failure which will generally deteriorate if beta-blockers are used.[5] Clinical utility of beta-blockers is therefore limited when treating older thyrotoxic subjects.

Hypothyroidism

Primary hypothyroidism occurs with increasing frequency in the older population. A large survey of general practice patients in England showed an incidence of three cases per thousand in women screened, with a 2% incidence of previously diagnosed hypothyroidism.[6] My subjective impression is that the incidence of previously diagnosed hypothyroidism in a typical geriatric population in this country is probably closer to 5% among women, and that the incidence of previously undiagnosed hypothyroidism is at least 1 or 2% when population screening is carried out. A recent survey of healthy elderly subjects found borderline elevations of TSH in more than 13% of those screened. When these patients were followed for four years, one third were found to have progressive thyroid failure, correlating the increasing incidence of hypothyroidism with age.[7]

Hypothyroidism is most often due to autoimmune thyroid disease, or the result of prior ablative treatment of hyperthyroidism. Secondary hypothyroidism is relatively uncommon. It is suspected when thyroid hormone levels are low, but TSH is not appropriately elevated. The major differential is between hypothalamic or pituitary insufficiency and the euthyroid sick syndrome. I have found idiopathic secondary hypothyroidism to be more common than the scanty literature on this disorder would suggest.[8] A hypothalamic or pituitary lesion should always be searched for initially, and periodic reassessment of the diagnosis should be made to detect the insidious onset of a central nervous system lesion.

Treatment of hypothyroidism in the elderly is complicated by the high incidence of atherosclerotic cardiovascular disease, the development of which is accelerated by hypothyroidism. It is common for elderly myxedematous patients to suffer heart attacks with or without the induction of thyroid hormone therapy. The incidence of coronary events is probably increased by starting thyroid hormone replacement. There is anecdotal evidence suggesting that it is safer to perform cardiac surgery on myxedematous patients with coronary artery disease while they are hypothyroid than to attempt presurgical therapy with thyroid hormone.[9] In myxedematous patients with significant atherosclerosis, treatment is instituted with extremely small doses of thyroid hormone, using doses such as 12.5 ug. of L-Thyroxine on alternate days. Even these minute doses may generate profound complaints requiring additional antianginal therapy. Some patients may refuse any amount of thyroid hormone replacement. The cause of the adverse response is often difficult to work out, and may not always be due to the presence of vascular disease alone. This difficult situation not infrequently occurs in patients with severe hypothyroidism, and underlies the importance of detection and prompt treatment of mild hypothyroidism. The need for lifetime treatment should be emphasized. Ideally, an aggressive approach to mild hypothyroidism in the elderly would minimize difficulties encountered when trying to treat severe hypothyroidism in patients with heart disease.

Elderly patients often outlive their physicians, and have their care assumed by younger providers. A new physician may be upset by the lack of documentation of the initial diagnosis of hypothyroidism, and indeed, such documentation often has not been obtained. A great many patients have been told they are hypothyroid based on insufficient data. However, discontinuation of thyroid hormone replacement often results in patients having low normal levels of T4 for prolonged periods.[10] Subjective symptoms often increase, causing rancor between physician and patient. In elderly patients on long term replacement with normal blood levels, my practice has been to assume the initial diagnosis was correct. This is probably safer and more cost effective than trying to document the diagnosis.

Other Considerations

The prevalence of nodular thyroid disease also increases with age.[6] As the proportion of substernal glands increases with time, the chance that an abnormality will be found is reduced. An educated examiner will often feel the top of the nodular thyroid rise from its substernal location upon deglutition. This is a finding best ignored, as the question of thyroid malignancy can only be resolved by an open surgical procedure. Although microscopic foci of thyroid cancer are frequently found in multinodular goiters, the incidence of clinical thyroid malignancy is low, and it is hard to justify a thoractomy for what is almost always clinically benign disease. When a dominant cold nodule in a multinodular goiter is easily palpable in the neck, I usually advise the performance of aspiration cytology to try to exclude malignancy. Thyroid cancer tends to be more aggressive in the elderly, and certainly surgical treatment is warranted whenever a diagnosis of thyroid cancer can be proven, unless life expectancy is measured in months rather than years.

While the incidence of papillary and follicular cancer peaks during middle years, cases do occur in the elderly. Unfortunately, the incidence of anaplastic thyroid cancer and lymphomas of the thyroid increases progressively with aging. These more aggressive disorders have a rather worse prognosis than papillary or follicular cancers.

There is no effective therapy for anaplastic thyroid cancer. A variety of treatments are available for the other types of malignancy, so that the incidence of thyroid cancer is many times greater than its mortality.

Summary

Thyroid diseases, and especially hypothyroidism, are frequent in the elderly. This paper discusses the varieties of thyroid problems and their management.

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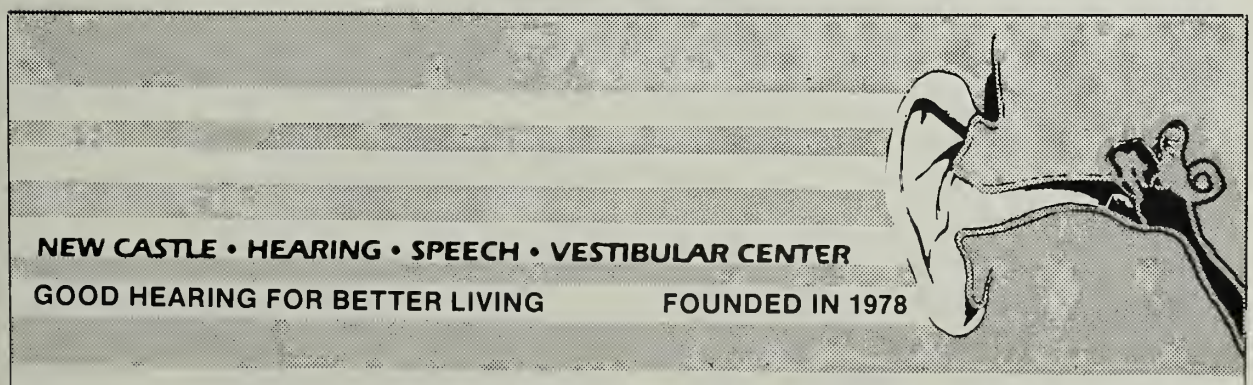

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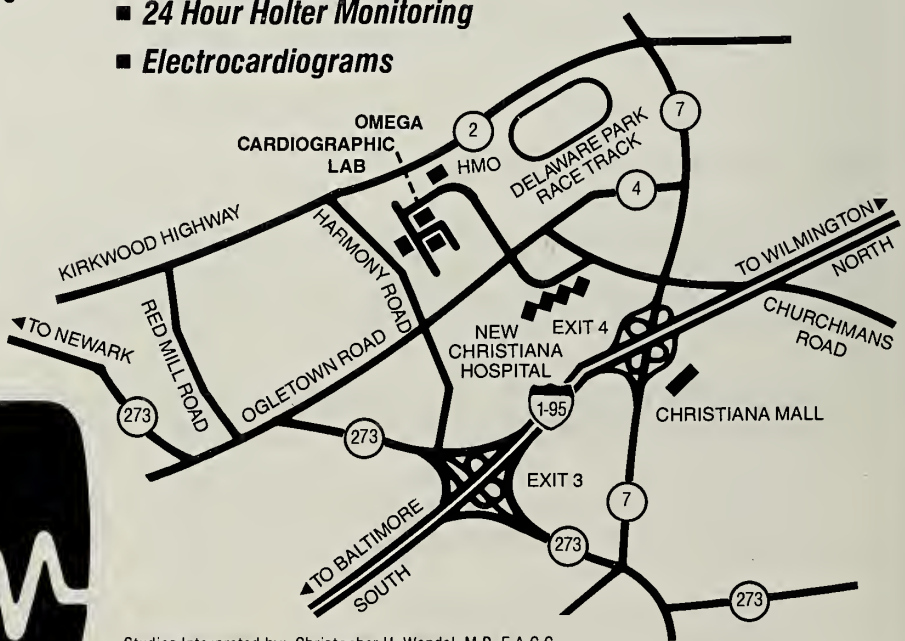

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HEALTH CARE OF THE ELDERLY: INFINITE PROMISE IN A WORLD OF LIMITED RESOURCES

Senator William V. Roth, Jr.

The famous British surgeon and First Baron, Joseph Lister, was once called to attend a rich lord who was choking on a fish bone that had become stuck in his throat. With dexterity, the great surgeon removed the bone. Overcome with gratitude, the patient asked Lister what was owed him. Lister replied with a smile, "My lord, suppose we settle for half of what you would be willing to give me if the bone were still lodged in your throat."

I begin with this anecdote because its thesis is the foundation upon which rests all the hard choices the political and medical sectors of American society are trying to make. The rich lord, to save his life, to find relief from the terrible discomfort of choking, would have paid any price to Dr. Lister. As a wealthy man, he could demand the highest quality of health care and evidently, he did just that. Today, Americans are of the same frame of mind. Life is sacred, and we will go to any length, pay any price, and demand the highest quality of health care available. If it's not available in our small town, we will travel to the big city. If it's not available in the big city, we will travel to another state. And if it's not available there, we will travel to another country. Ponce de Leon came to America to search for the Fountain of Youth, and we have never stopped looking.

On your part, the medical community has effected miracles. Before the middle of last century, doctors could set broken bones, lance boils, and treat symptoms, but they could not cure disease. Since that time, progress of the most dramatic kind has been made. One hundred years ago, medicine could not cure tuberculosis; today you have unlocked the secret of DNA. One hundred years ago parents were terrorized by the epidemic killers of childhood; today polio and pox are words found in the annals of medical history. One hundred years ago a newborn girl could expect to live 44 years; today her life expectancy is 78.

These few remarkable facts portend a future of even greater progress and more miracles. In fact, I recently heard of a study that says many babies born today who maintain a healthy lifestyle by staying away from high risks such as tobacco and excessive alcohol can be expected to live well past 100. What an exciting time to be alive, a time of progress when all of us can look forward to rich, fulfilling years that were only imagined by previous generations.

As good as this news is, however, we cannot say that all is well. While technological breakthrough is the order of the day, the ethical and financial questions that accompany the breakthrough can be troubling. In his book, *The Health Century*, Dr. Edward Shorter tells the story of Hezekiah, a godly man who lay dying. Turning his face to the wall, Hezekiah prayed to God to grant him 15 more years. He had been a good man, and it came to pass that the Lord fulfilled his prayer. Today, we are all modern Hezekiahs. Technology alone can sustain life for 15 years or more. And the implications of this one fact bring questions:

When does the quality of life end?

When should life, sustained by costly machines and preserved technologically, be terminated?

What factors are we going to allow to govern the precious, life-giving resources such as artificial implants and organs, as we determine when and upon whom they will be used?

In an age of boundless technology, how accountable

Adapted from a speech given by Senator Roth to the Medical/Dental staff of The Medical Center of Delaware.

can we hold physicians and technicians in their decision making processes?

And in a country where our universal ethics hold that life is sacred, how much are we willing to pay to sustain it? And who will foot the bill?

These are only a few of the issues that confront medicine and Washington. There are others equally as complex. Americans have made it clear that they want universal access to health care services at a reasonable cost. The only option they have been given so far to accomplish this is the liberal recipe of more taxpayer-financed and government-managed social insurance programs. And these are taking their toll.

Since 1981, the cost of medical care has increased at an average nearly twice the rate of inflation. Between 1980 and 1985, total national expenditure on health care jumped from 5.3% of our Gross National Product to 10.6%. Spending on federal health care programs has continued to soar as well. From 1975 to 1985, federal spending for Medicare and Medicaid grew from $25 billion to $103 billion. In 1985, America spent $425 billion on health care, and the government paid 41% of the bill.

The field of American medicine can be described as infinite promise in a world of finite resources. Today, we can realize more than we can pay for. We are far from making the hard choices that accompany our present situation, and like the band that plays on as the ship sinks and never sounded better or played with such energy, we're not really doing what it takes to save ourselves or the ship.

In fact, I'm reminded of the story of Konrad Adenauer, the German statesman and first chancellor of the Federal Republic. While he was still chancellor and approaching the age of 90, he succumbed to a heavy cold. His personal physician, unable to be of much help, had put up with Adenauer's impatience. "I'm not a magician," protested the doctor. "I can't make you young again."

'I haven't asked you to," snapped the chancellor. "All I want to do is go on getting older."

Today, as we confront the dilemma of rising health care costs, we're not looking for a magician to take us back to the days when health care was only 5.3% of our GNP, the days when Medicare and Medicaid payments were only $25 billion. All we want to do is go on getting older, taking care of our health care delivery system so the progress we have realized in the last 100 years can continue into the next 100. We must be able to answer the questions posed by the challenges of sophisticated technology, patients who demand the highest quality of care, and a country that is graying and becoming more medically dependent. And we must find those answers without turning back the clock.

Personally, I believe the way to do this is by allowing the medical community the flexibility to find the answers. The free market principles that direct the American medical community are responsible for the advancements we have seen over the years. Those free market principles have constructed a nation with a health portfolio that is second to none. And government must not be too quick to disrupt what has been a very good thing.

Unfortunately, the role of the government and what government is expected to do in the American health care delivery system has mushroomed to the point where budgetary constraints in government are forcing policy decisions that are not good for the medical community. There is serious concern that the Congressional-sponsored insurance programs are leading down the path of socialization. I don't have to mention the setbacks associated with this scenario.

Yet the debate persists. Since Bismarck introduced sickness insurance in 19th century Germany, debate concerning the appropriate breadth and depth of coverage has been waged at all levels of government on all continents. One example that we are dealing with now is the Medicare Catastrophic Illness Coverage Act presently in conference. The implications of the act take on new meaning as we consider the needs presented by the aging of America.

When President Reagan took office in 1981, Americans over age 65 received $50 billion in government-supported medical care. Should the present rate of growth continue, the figure will be more than $200 billion by the year 2000. Even under the current administration which has been largely criticized for what its detractors call an "unsympathetic" approach to the aged, social payments to the elderly have risen 35%, so that now 30% of all government spending goes to 12% of the population. Should the current growth rate continue, by 2020 the percentage would be almost two thirds of the nation's total budget.

It is a logical assumption that as the graying of America continues, the cost of social programs to care for the health needs of the aged will rise. Analysts are predicting that in the next four decades there will be a 160% increase in physician visits by the elderly, a 200% rise in days of hospital care, a 280% growth in the number of nursing home residents. Between now and the year 2000, a new 220 bed nursing home will have to be opened every day just to keep up with demand.

With the financial conundrum of matching resources to needs, Congress must now decide on a program that could turn out to be the most expensive entitlement program enacted during the past 15 years. The cost for Catastrophic Insurance alone would be more than $34 billion. Passage of the Catastrophic Insurance Act would raise the premiums Medicare recipients would pay for coverage already provided, and even the premiums would not pay for the extended benefits promised under the act.

The irony is that company health care policies and

"Medigap" coverage already provide better services at better prices. Consequently, the possibility exists that as Medicare premiums rise, beneficiaries may opt out for private alternatives and cause the government program to crumble. Within this scenario the government would have created another program to build false expectations among our elderly, expectations that would not survive the demands of the demographics I have outlined.

I share the desire of my colleagues to protect our elderly citizens from the potentially devastating effect of catastrophic health care expenses. There are three different areas in health care protection where definite needs must be addressed: catastrophic protection, nursing home or long term care, and prescription drug coverage. Because of the high cost involved in each of these areas, the mounting needs of the elderly, and the expectations that will result from the actions of Congress, it is important that we proceed carefully. Any action we take should be well conceived and financially sound.

Congress must not support legislation that will duplicate existing coverage provided by the private sector that will balloon costs for our senior citizens and jeopardize the solvency of the Medicare trust fund. In the long run this coverage would threaten not only the integrity of the government to provide expected health care, but would strap the medical health care delivery system with rules and regulations that would bruise its incentive for progress and cut into the quality of American health care.

On the other hand, our decisions must be guided by the principles of incentive and care that have been the hallmarks of our medical community for the past century. We can expect change, but the change must be advantageous for all parties involved: the patient, the physician, and the financier. A win-win-win situation is the only way America will continue to deliver quality health care over the long term.

To establish this beneficial relationship, all parties must be equally involved. I am astonished when I read the astronomical figures for health care that could be avoided if all Americans would commit themselves to a healthy lifestyle. The saying, "The health of a nation is the wealth of a nation," is true in more ways than one. Tens of billions of dollars are wasted each year because Americans are not practicing preventive care. When I hear that 64% of our youth ages six to 17 cannot pass a basic fitness test, I grow concerned. When I hear that one of every four Americans is obese, plagued by a dangerous lifestyle that can be reversed, I grow concerned. And though we have much to encourage us concerning the decline in smoking and alcohol abuse, and even the uses of certain drugs, I am still concerned that the figures are not getting lower faster. There is such a thing as physical morality, and Americans must take a personal interest in keeping themselves healthy and happy; only then will we be able to get a handle on health care expenditures.

For its part, the medical establishment must be collectively self-conscious. There is no pressure like peer pressure, and principles of good, effective business must prevail in hospitals and medical centers. Certain changes in the health care delivery system like the Prospective Payment System in Medicare have ushered in an era of revolutionary change.

Attitudes are changing, and business know-how is being applied in many areas of the health care delivery system to keep prices under control. I read where one hospital cut thousands of dollars from its budget just by changing the surgical gloves used in their operating rooms. The new gloves had the same protective quality, it's just that the hospital had grown comfortable with its old supplier and its prices over the years which without competition had crept higher and higher. Medical suppliers must be ever-vigalent in assuring the best possible quality in materials at the most cost-effective prices, especially in light of the present increase in demand for disposable medical supplies made necessary by the threat of AIDS.

However, I also know only too well that the Prospective Payment System is not without its problems. In concept, it is a good idea, but it is not perfect. I have probably heard more from doctors in the last three years than I did in my first 20 years on Capitol Hill. And I'm hearing from them for good reasons. Their concerns and even complaints are legitimate. They have concerns about the "quicker-sicker" that government regulations are often forcing physicians to discharge patients too early from the hospital. Consequently, patients are being discharged while they are still ill. Frankly, I believe the government is not in a position to violate the physician-patient relationship. As a matter of fact, I have been in constant contact with the West Virginia Medical Institute, the Delaware peer review organization, concerning denied claims from Delaware hospitals.

The government most allow the medical community the latitude to make its own decisions. Right off hand, I can think of no medical doctor presently serving in the United States Senate. Maybe that is the problem. However, I don't want anyone from Delaware to be the first, especially this year! And quite frankly, I believe Congress should not be telling the physicians back home how to do their jobs. However, to curb costs, the government has had to make changes. One of these was the Prospective Payment System, and I for one, am impressed at how the medical community responded with alternative methods of delivering patient care. You have created and expanded new delivery systems. The growth of Health Maintenance Organizations and home health care are only two examples. In fact, I understand that The Medical Center of Delaware has entered into a partnership with the Visiting Nurse

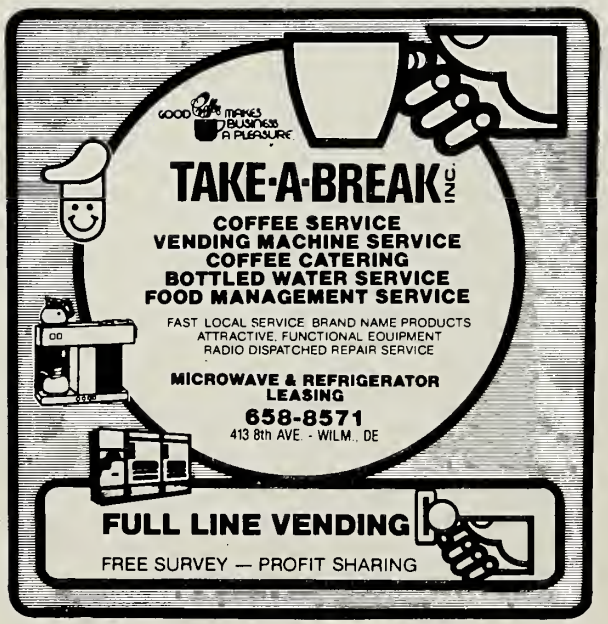
Association to expand its patient care to the home environment, and I'd like to say congratulations.

Another example of where the medical community is expanding to meet the infinite needs in a world of finite resources is with hospice care, which I worked to have included as Medicare reimbursable. Hospice is a way to provide quality, caring services in a cost-effective, efficient way.

But these are only a few examples. There are many others. One trial program is technology pooling, whereby two medical centers keep their overhead down by sharing costly equipment. We have seen success with this program in our own state. I believe that unencumbered by topheavy regulations that come with government intervention, the health care delivery sector of our society is making good progress. As a matter of fact, Congress has offered a bit of a reprieve, agreeing not to make any changes to Medicare other than those initiated in the two year budget summit agreement. In other words, you're safe for now.

However, I also believe there are many things that can still be done to improve the situation. But I would rather see the answers come from the private sector which has built such an impressive record over the last century. It would seem to be easier to deliver quality and affordable health care than to unlock the mysteries of the DNA molecule. And I believe the same group that can do the latter can certainly do the former.

Consequently, I believe any action by Congress to interfere with the business end of the American medical establishment should be aimed almost exclusively at creating incentives for better and efficient care, not creating regulations. This is the only way the 100 years of medical miracles will become 200 and then 300 and 400. If we are to realize success, it must be joint success.



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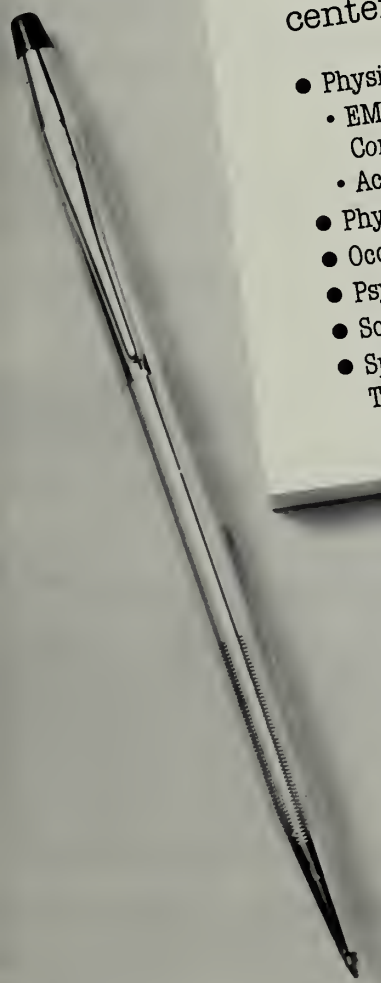

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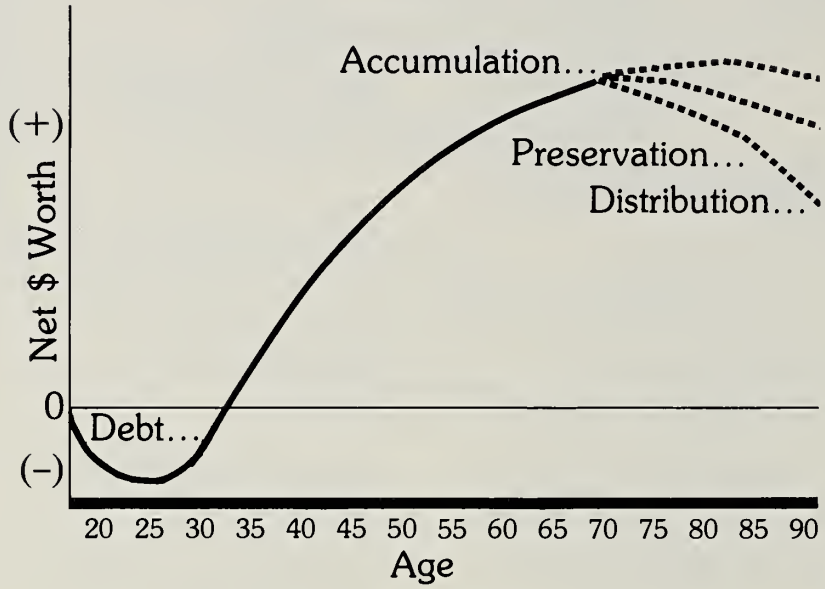

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Medical Ethics

IS MEDICAL ETHICS A TRADITION AND IDEAL WITHOUT A FUTURE?

This has been provided as a service of the Ethics Committee of the Medical Society of Delaware. Robert W. Frelick, M.D. Chairman.

Edmund D. Pellegrino, M.D.

"Let no man make you bad because he is."
Seneca, *De Beneficiis*

Many members of the medical profession and the public were shocked recently when a prominent cardiac surgeon refused to operate on patients with HIV infection and argued, to boot, that he was morally justified in doing so. He bluntly challenged the long-held assumption that altruism is intrinsic to medical morality. Instead, he asserted that physicians had a moral right to place their own and their family's interests ahead of those of the patient.

I believe this surgeon's actions and the arguments advanced to support it are morally untenable. But he has exposed for public debate a growing conviction among many physicians today that it is no longer requisite, nor possible, to adhere to the nobler ideals of the profession. This conviction, if it gains more support, threatens to be fatal to medical ethics as we have known it.

Many pragmatically minded physicians now agree with the cardiovascular surgeon. They argue strongly that medicine is no different from any other service in society. Its practitioners are expected to be competent and to avoid deliberate harm to their patients. But they are not obliged to practice higher degrees of effacement of self-interest like risking AIDS contagion or malpractice litigation, forgoing the profits of medical entrepreneurism, or caring for the poor or the uninsured.

There is a weaker argument that is equally disastrous for medical ethics. This is advanced by idealists who genuinely believe that effacement of self-interest is a moral duty of physicians. Given the "climate" of medical practice today, these physicians argue, survival is impossible without compromising medical ethics. By "climate," they mean some combination of crises now pouring out of the cornucopia of social change malpractice litigation, AIDS, physician surpluses, legitimation of advertising, corporate medicine, entrepreneurism, the strictures of cost containment, public and media hostility, and the general decline of morals in all the professions.

While the pragmatists respond aggressively, the idealists suffer moral lassitude. They succumb to a kind of Gresham's Law in which the bad moral currency drives out the good. So they retire early, discourage their children from entering medicine, and become embittered cynics. They give silent approbation to Machiavelli's dictum that virtue simply does not work in an evil world.

I believe, however, that there are counter arguments that can give pause to the pragmatists, and encouragement to the listless idealists. Moreover, I believe that we will be morally overwhelmed only if our profession fails to use the moral power it already has.

A moral obligation of effacement of self-interest can be grounded in at least three things internal to medicine. First is the special nature of the experience of ill-

ness, the vulnerability and exploitability it engenders. The sick person is dependent upon the knowledge and skill of the physician and is forced by his circumstances to trust him. Without that knowledge and skill the patient may die, become disabled or suffer unnecessary pain and anxiety.

Second is the fact that the physician's knowledge is not proprietary. It is the product of an education the physician was privileged to obtain by invasions of the privacy of sick people. Medical students are permitted to dissect human bodies, assist at autopsies and operations, participate in daily care at the bedside, and they are made privy to the personal details of other people's lives. Society permits all of this so that the medical knowledge may be passed on to the next generation. Medical knowledge, therefore, is not a commodity that doctors own, but an object of trust over which they hold stewardship.

Finally, the physician is morally bound by an oath that acknowledges both the vulnerability of the sick and his stewardship of medical knowledge. When he takes this oath he formalizes the implicit covenant he entered as a student when he accepted the privilege and obligations of a medical education.

This role-related specific moral obligation is analogous to that of the policeman, fireman or soldier. It entails exposure to certain risks--physical, financial and personal. To be sure, it does not require suicidal heroism, a monastic vow of poverty or neglect of reasonable obligations to self and family. Few physicians today are asked to make choices that are so momentous. The risk of AIDS, even for surgeons, is not suicidally high. And few physicians would be reduced to penury by more pro bono work or by distaining the profits of the medical entrepreneur.

Obviously, some balance must be struck between heroic self-sacrifice and neglect of our covenant with the sick. There is no universal formula that will define the point of balance for everyone. What is clear is that some physicians are already weighting the balance too heavily on the side of self-interest. To make matters worse, they deny the validity of a moral substructure for their calling.

What can the ethically sensitive and responsible physician do in such a morally intemperate climate? For one thing, he can maintain his own moral integrity by practicing rational diagnosis and therapeutics, and by avoiding those financial conflicts of interest that arise from seeing medicine as primarily a business; by recognizing and respecting the role-specific altruism built into medicine by its very nature; by refusing to cooperate in policies that violate the patient's interests, and by being an advocate for the sick whenever economics, organizations or regulations threaten the patient's good.

Of course, no individual physician can reasonably be expected to carry the full weight of moral redemption for the whole profession. The profession itself has enormous unused power for moral good. No one can compel hundreds of thousands of physicians to do what they believe violates medical ethics so long as they build their ethics and their cases on the primacy of the patient's welfare rather than their own self-interests. What would happen if the majority of physicians were joined by a majority of nurses and other health professionals in advocacy for the interests of the sick? Would all those forces that create the "climate" that so many think is irresistible withstand such a moral assault? Would the forces of public opinion not add to the pressure?

Seneca was right--none of us need accede to moral compromise just because others are doing it. Medical ethics need not be a failed ideal. If it becomes so, it is because we--public and professional alike--want it so.

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Editorials

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THE NEWEST SUBSPECIALTY

Geriatrics is an evolving discipline, whose territory and borders are still indistinct (see page 393). However, particularly as the science base for geriatric medicine expands, it will become a subspecialty of medicine.

I have no doubt that most geriatric problems will continue to be managed well by primary physicians, but like diabetes, some aspects of the condition may require a physician with extra training and interest for optimal management. For example, the diabetic who becomes pregnant needs a doctor who is able to coordinate the multidisciplinary arsenal necessary to ensure near-euglycemia and a healthy baby. This physician may be called a diabetologist. Similarly, the geriatric patient who can no longer cope with independent living may need a physician, a geriatrician, who can coordinate the multidisciplinary assessment and optimization of remaining function to ensure the most appropriate outcome.

It was a pleasure for me to edit this issue. I think that you will find the articles interesting and practical.

Herbert J. Keating, III, M.D.

TAKING CARE OF THE WELL ELDERLY

In 1984, the American College of Physicians reported that about 30% of its practitioners' time was spent caring for the elderly, a segment of the population that continues to grow.[1]

Despite the enormous costs of health care for the frailest portion of this population, most people survive to old age with vigor.[2] At age 65, for example, people are expected to live another 15 years, enjoying functional independence for ten of those years. It is for these people that attention to preventive health may be most appropriate.

Old people have often been reluctant to seek medical advice.[3] However, it is expected that health conscious middle aged people entering old age, recently a period of relative affluence, will be more likely to seek medical attention for preventive care.

I propose a structure of preventive care in the well elderly, modifying the work of Stults.[4]

Goals for Preventive Care in the Elderly

If one accepts that the life span is finite, the goal of preventive health care is mainly to contribute to the maintenance of vigor, and particularly to the maintenance of independent function.[5] Often the geriatric patient values the preservation of *dignity* of life as much or more than the condition of life.

A clear physiological decline occurs with aging. Although this decline is highly variable among individuals, it affects all organ systems. Whether this "progressive incapacity of aging"[6] represents the accumulated effect of sub-clinical disease, disuse, or an unopposable, genetically-mandated decline is uncertain. This decline may cause few or no symptoms in a resting state, but with stress from an acute insult may manifest itself dramatically. If the patient's organ systems are unable to maintain organism homeostasis, the patient dies.

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The traditional stages of preventive care are primary, secondary, and tertiary, addressing prevention of disease, early detection of disease, and rehabilitation of disease, respectively. Because of the unique characteristics of the geriatric patient, preventive care in the elderly might be more appropriately staged as follows (Table 1).

Stage 1. Prevention of acute challenges whose occurrences may threaten life or the dignity of life, eg, pneumococcal pneumonia or inappropriate institution of cardiopulmonary resuscitation.

Stage 2. Detection of those diseases or conditions which may accelerate the loss of independent function as a result of the loss of organ system reserve, eg, hypertension, alcoholism.

Stage 3. Reversing or slowing, if possible, the normal functional decline associated with natural aging, eg, exercise programs.

Although there is imprecision in these divisions, I would like to briefly discuss preventive care in the elderly by these stages.

Clearly the frailer the patient, particularly the older the physiologic age, the less preventive care measures have to offer. This is particularly true if measures are unpleasant or undignified.

As prescribed in the sage advice, "Don't fix a clock that ain't broken," the physician should avoid making medical mountains out of molehills. A cholesterol of 250 mg/dl is not hypercholesterolemia, and does not need therapy in a 78 year old. Physicians should also dispense a great deal of reassurance, emphasizing the positive aspects of the patient's independent function.

TABLE 1
PROPOSED STAGES OF PREVENTIVE CARE IN THE ELDERLY

Traditional	Geriatric
Stage 1. Prevention of disease	Prevention of acute, life-or quality-of-life-threatening insult.
Stage 2. Early detection of disease	Early detection of disease or condition which accelerates loss of independent function, especially as a result of loss of organ system reserve.
Stage 3. Rehabilitation	Reversing or slowing the "normal" functional decline of aging.

Stages of Preventive Care in the Elderly

Table 2 summarizes care which seeks to prevent

TABLE 2
STAGE 1 OF PREVENTIVE CARE IN THE ELDERLY. PREVENTION OF ACUTE THREATS TO LIFE OR THE DIGNITY OF LIFE

Immunizatians
- influenza
- pneumocaccus
- tetanus

Preventian af self-inflicted injury
- falls
- matar vehicle accidents
- burns

Preventian af MD-inflicted injury
- limited treatment plans (eg, living will)

acute, threatening challenges to the elderly. Immunizations against influenza,[7] pneumococcal infections, and tetanus[8] are appropriate for most older patients, but steps towards accident prevention may be even more important. Preventive attention should also be directed to the appropriate use of limited treatment plans,[9] including the living will.

Stage 2 of preventive care in the elderly (Table 3) seeks to identify those treatable conditions which contribute to accelerated loss of functional independence, principally through accelerated loss of organ system functional reserve.

Important among these conditions are neoplastic diseases, which have a steeply increasing incidence in the elderly. Although the data often are not conclusive, the primary physician should encourage breast self-examination and yearly or bi-yearly mammography in women over 65 years old. Flexible sigmoidoscopy is probably the screening test of choice for colo-rectal carcinoma. The standard recommendation of an examination every three years following two negative examinations is reasonable. There are no standard recommendations for detection of gynecological or prostate malignancies in the elderly, although yearly digital rectal examination is advocated. Fecal hemocult testing is of very limited usefulness in a nursing home population.[10]

Endocrine diseases, particularly the estrogen deficient states, may be appropriate areas of secondary preventive care. Urinary and sexual function may be better maintained, and distressing local symptoms minimized by the identification and treatment of vaginal atrophy. Estrogen replacement also offers benefit in post-menopausal osteoporosis, a disease which may be different than senile osteoporosis.[11] Detecting significant osteoporosis at a time when intervention offers most promise may require bone density studies in the pre-geriatric age group.

TABLE 3
STAGE 2 OF PREVENTIVE CARE IN THE ELDERLY. DETECTION OF STATES WHICH ACCELERATE LOSS OF FUNCTIONAL OR ORGAN SYSTEM RESERVE

Cancer
- breast
- calarectal
- ? prastate
- ? gynecalagic

Endacrine disease
- asteoparasis
- diabetes mellitus
- atraphic vaginitis
- thyraid disease
- ? parathyraid disease
- ? hyperlipidemia

Cardiavascular disease
- hypertensian

Sensary dysfunctian
- visual ar hearing disorders

Miscellaneaus
- urinary incantinence

Psychiatric/neuralagical/behaviaral disease
- depressian
- dementia
- alcahalism

Special disease
- isolatian
- malnutritian

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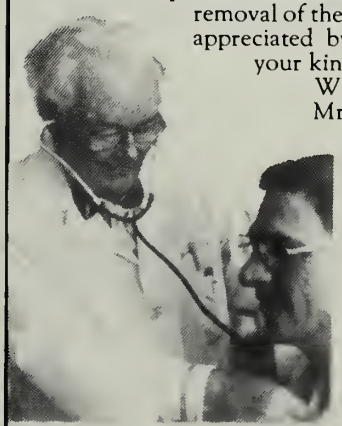

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Both occult hyperthyroidism and hyperparathyroidism may accelerate bone loss, and with diabetes mellitus and hypothyroidism, contribute to the decline of functional reserve. Therefore, I believe that yearly screening of thyroid function, serum calcium, phosphorus, and fasting blood sugar should be performed.

No data exist about screening for hyperlipidemia in the geriatric population, although it's a hot topic with the well elderly.

Convincing data about the benefit of detection and treatment of hypertension are confined to patients under 69 years old.[13] Pseudo-hypertension, a result of stiff, non-compressible vessels, may confound the determination of the true blood pressure in the very elderly. This is detectable by a positive Osler maneuver, and the ability to palpate a radial pulse despite cuff inflation above the measured systolic pressure.

Because of the prevalence of hearing loss and the potential for aural rehabilitation using hearing aids and patient/family education, yearly screening for hearing loss by a good history is appropriate. Brief inspection of the auditory canals to exclude occlusive cerumen or active otitis should be followed by formal audiology evaluation in all patients with a positive history of hearing loss.

Yearly examination by an ophthalmologist beginning at age 65 years is recommended. However, the functional consequences of visual impairment are often best assessed by the primary physician. For example, can the patient continue to drive? Can he measure his own insulin doses?

Urinary incontinence commonly causes loss of independent function, but is often reversible.[13] A caring, solicitous history will identify the problem.

In another article, Dr. Raskin describes the important psychiatric problems in geriatric patients. Depression and dementia are frequent and often reversible, sometimes dramatically so. A list of some curable dementias is found in Table 4. A formal, easily applied test such as the mini-mental status exam is recommended to detect subtle cognitive impairment.[14]

A comprehensive assessment of function has been advocated every two years in patients 65-74 years old, and yearly thereafter. The purpose of this exam, which may best be done at home, is to evaluate the social supports that the patient needs to continue to function as well as possible.

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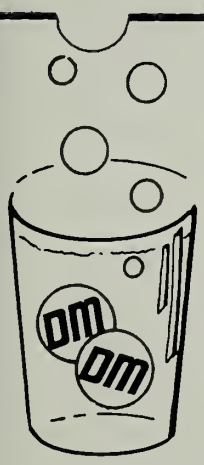
TABLE 4
THE "CURABLE" DEMENTIAS

Systemic illness	
	endocrinopathies
	lung disease with hypoxia or hypercarbia
	chronic renal failure
	chronic hepatic failure
	dehydration
	cancer
	hypoglycemia
Intoxication	
	sedative and neuroleptic agents
	barbiturates, bromides, heavy metals
	others, eg, propranolol, cimetidine
Other rare causes with variable reversibility	
	chronic subdural hematoma
	normal pressure hydrocephalus
	neurosyphillis
	meningitis
	brain tumor
	thiamine deficiency
	Vitamin B_{12} deficiency
	niacin deficiency
	transient global amnesia



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Stage 3 of preventive care in the elderly seeks to slow or reverse the normal functional decline. There is some evidence that physical inactivity may cause or contribute to functional loss.[15] Probably mental inactivity has similar effects. The primary care physician should prepare physical and perhaps mental prescriptions for elderly patients.[16] The role of vitamins and other elixirs remains unestablished.

Summary

The care of well elderly patients aims at maintaining independent function, an often attainable and rewarding goal for the practicing physician.

Herbert J. Keating, III, M.D.

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THE GRAY BOOMERS

Dr. Keating, guest editor for this issue on geriatrics, has been in Wilmington only five years. During that time, he has established himself as a very valuable and highly esteemed member of the local medical community. This issue of *Delaware Medical Journal*, the eleventh of our focused issues, was entirely arranged by Dr. Keating, and produced in record time.

This issue comes out just a month after the first group of physicians--I will be interested to know just how many--sat for the certification exam in Geriatrics. I personally find this a stratification by age which may be an invitation to agism in medicine, and may create more problems than it will solve.

The American Association of Retired Persons (AARP) numbers millions in its membership. Fifty year olds are not eligible for senior citizen discounts any place I know, but they are eligible for membership in AARP. At what age will a patient be suitable for referral to a geriatrician? Will geriatricians extend the margins of their turf downwards as the pediatricians have extended theirs upwards?

The authors in this issue present a varied and interesting group of papers about the medical problems of our senior citizens.

Bernadine Z. Paulshock, M.D.

THE STATE OF THE ART

Her chief complaint is that she wants to die and that the doctors will not let her.

She is 96 years old. She has attended the burial of her husband, two daughters-in-law, and all the people who were close friends throughout her lifetime. A woman of fierce and independent spirit, she never wanted to live with her children, to be supported by them, or to be what she calls "a burden." After being widowed 24 years ago, she achieved these goals for a long time because she was in good health and her modest fiscal needs were met by the interest of the trust fund left by her husband.

Until 11 years ago, she lived alone and maintained her own apartment. She spent her time walking, talking with neighbors, reading, watching television, playing card games, attending religious services, and traveling to visit her children, grandchildren, and great-grandchildren in different cities. At age 85, however, she began to dislike shopping and cooking for herself; and she began to worry about living 60 miles away from her nearest relative. She moved, in a city where a son and grandchildren lived, into an apartment residence building that was the "congregate setting" of a geriatric center. The setting provided her with lunch, dinner, a social life, and her own small apartment, in which she prepared her own breakfast.

On her 90th birthday, although in excellent mental and physical health, she began complaining that she had become too old. Her stated desire was to die in her sleep, preferably not on a night before she was scheduled to visit her great-grandchildren. When hospitalized with an episode of pneumonia that winter, she said, "My time has come." She bid a loving good-bye to each child, grandchild, and great-grandchild who came to see her, and gave them a farewell blessing. When she recovered--thanks to intravenous fluids and

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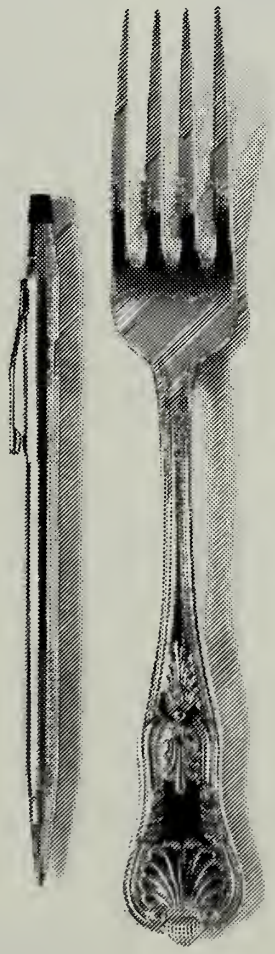

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antibiotics--she was surprised and somewhat dismayed, but she resumed her former life, remaining independent and "perky."

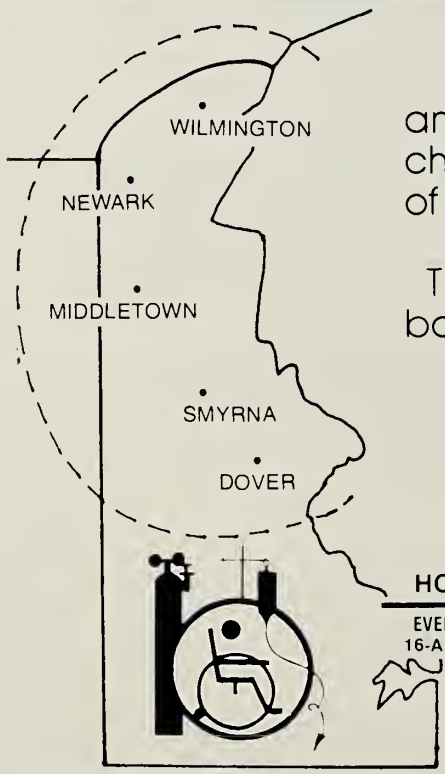
During the next few years, she grew progressively more frail. She began having episodes of faintness, due to paroxysms of atrial fibrillation, but the episodes were brief, and the symptoms would vanish when she lay down briefly. She began walking with the aid of a cane. Although she would no longer travel long distances alone, her mind remained clear and her life independent. With each winter, however, she was rehospitalized with another bout of pneumonia. Each time she was sicker than before; each time she was prepared and wanted to die; and each time she received vigorous therapy and recovered.

During an episode three years ago, however, she had a spell of faintness while in the toilet of her hospital room. Uncertain that she could successfully get back to her bed, she treated the symptom in her usual manner. She lay down calmly on the floor, closed her eyes, and waited. In that position, and with a rapid irregular pulse, she was found by a nurse who promptly issued an emergency "Code" alarm. By the time the doctors and equipment arrived, she actually felt much better, but the excitement of the aggregated "team" convinced her she must be moribund. When she failed to die, she became angry and depressed. "I want to die, and I am ready to die," she said, "but the doctors won't let me."

After she returned to her small apartment, she became less depressed as she became persuaded that she needed to live at least another year to attend the religious confirmation of her youngest granddaughter. During that year, she became more frail, but her mind stayed clear and her spirits high. She traveled four hours in each direction by private car to go to the confirmation ceremony, and she took special pleasure in participating in it. During the trip, she laughed, sang, and joked, exchanging stories of the old days with a brother-in-law whom she seldom sees and who had come a long distance to ride with her to the ceremony.

Several days after her return home, she had a stroke. She became confused and disoriented. Although physically able to function, she could no longer take care of herself. She could not cook or successfully make her way alone to and from the dining room. When lucidity transiently drifted in, she would complain unhappily and bitterly about having a "companion," who had been hired to be with her during waking hours, and about having become "a burden."

About a week later, she re-entered the hospital with another, more severe stroke. She was conscious, seemed aware of her surroundings, and could state the names of her family visitors, but she made no other conver-



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sation. Moving her eyes toward the sky, she seemed to be pleading with God to take her at long last. When she developed anorexia, fever, and pneumonia, her children asked the house staff to let her alone, but they could not "do nothing." Before one of her sons--a physician at a medical school in a distant city--could arrive to dispute the doctors' plan, she was given intravenous antibiotics, fluids, and other vigorous support.

She recovered, left the hospital, and now resides in a nursing home. She can still recognize her family visitors, say their names, and engage in trivial conver sation, but her mind is substantially destroyed. She does not know where she is or how long she has been there. She cannot read, watch television, walk alone, use a telephone, or play card games. She retains bladder and bowel continence, but she cannot dress herself, feed herself, or transfer from bed to chair to bathroom.

She is no longer aware of her plight, and expressed no suggestion of despair, but everything she wanted to avoid has happened. In a semivegetating state, she has lost her functional and mental independence; and she is about to become a financial burden as well as a physical burden. Because she has a trust fund, the government will not pay for the costs of the nursing home; but the trust fund interest is not large enough to cover the charge of $80 a day. She had hoped to leave the trust fund principal to her grandchildren, but now it will gradually be transferred to the nursing home.

As her visitors deal with the agony of her vegetation, they wonder why this problem has been created. Since the preservation of her life helps no one, and is desired neither by her nor by those who love her most dearly, why could her doctors not be content to let her die in peace and serenity? Why did they pursue a vigorous therapy that could benefit no one except their own satisfaction in thwarting death, regardless of the consequences?

I do not know the answers to these questions. But I, the physician son of this woman, weep for my mother and for what has happened to my profession.

Alvan R. Feinstein, M.D.
New Haven, Connecticut

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"TAILS"

An important aspect of practice, often overlooked by established physicians, whether there be one or more in the group, is who pays for the medical malpractice insurance tail should a physician leave, die, retire, or become disabled. Since tail coverage can be more than 100% of the amount of the final year's premium of a typical claims made policy, this is an issue all physicians in Delaware who practice should face--before the problem arises.

There are two schools of thought in this issue: the group pays or the individual pays. Many physicians are of the opinion that medical malpractice insurance and thus the cost of the tail coverage for physicians leaving the practice is a part of doing business. If the group has routinely paid a physician's malpractice premiums, it would seem logical that the group would automatically pay for the tail as well. However, others believe that since the malpractice policy offers personal protection for a physician, it is up to that doctor to come up with the premium amount of the tail--which could be as much as $75,000, due in a lump sum.

Physicians should be aware that most insurance companies operating in Delaware at this time offer free tails under certain circumstances, and as long as coverage dates and age requirements are met.

Since there is no right or wrong in this situation, group members should decide on a policy (if they haven't already done so) which addresses the issue of tail coverage for members of the group who might leave. Whether it is an escrow account all members contribute to, or part of the general fund specifically earmarked for insurance premiums, this is a problem best settled when the physician first enters practice.

Martin J. Cosgrove, M.D.

INVITATION TO EXHIBIT
199th ANNUAL MEETING
MEDICAL SOCIETY OF DELAWARE

Applications for SCIENTIFIC EXHIBITS for the Annual Meeting of the Medical Society of Delaware are invited by the Scientific Exhibits Committee.

It is hoped the exhibit portion of the Annual Meeting to be held at the Hotel du Pont in Wilmington, November 19, 1988, will be stimulation to demonstrate scientific achievement. Physicians are invited to apply now for space. The fee for exhibit space for members of the Medical Society of Delaware is $200. All booths are 6 feet wide and 2½ feet deep.

Mail applications to Robert C. Knowles, M.D., Chairman, Scientific Exhibits, Medical Society of Delaware, 1925 Lovering Avenue, Wilmington, Delaware 19806. Deadline for filing applications is August 1, 1988.

.....

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OPEN HEART SURGERY FOR CONGENITAL HEART DEFECTS: OVERVIEW AND REVIEW OF THE EARLY EXPERIENCE AT THE MEDICAL CENTER OF DELAWARE

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N. Peter Karmilowicz, M.D.
Paschal M. Spagna, M.D.
Gerald M. Lemole, M.D.

Introduction

The goal of the open heart program at The Medical Center of Delaware is to provide excellent care to the entire spectrum of patients with heart disease from the newborn period through later years. The successful surgical management of young patients with congenital heart disease requires a specialized facility and faculty, and is the topic of this report.

Personnel and Equipment

The two open heart surgical operating suites contain anesthetic equipment, operating room (OR) tables, and overhead heaters adapted to facilitate care of newborns and young children. Pediatric extracorporeal oxygenation circuits allow smaller primary volumes and flows for pediatric perfusion needs. Specific details related to patient transport and immediate postoperative care have been addressed. There is a Cardiovascular Intensive Care Unit specifically equipped for pediatric patients following open heart surgical procedures, as well as a telemetered step down unit.

The OR team was chosen to include nursing personnel experienced in pediatric open heart procedures. Staff perfusionists have had extensive experience and specific qualifications in techniques of extracorporeal membrane oxygenation, circulatory support, circulatory arrest, and profound hypothermia, in addition to standard pediatric perfusion protocols and techniques. Extensive inservice training was done and a detailed manual was compiled for perfusion, nursing, and medical personnel. The two attending anesthesiologists trained at a well known children's hospital and have brought with them extensive experience and expertise.

The pediatric surgical team is headed by a pediatric cardiovascular surgeon who personally directed a successful high volume pediatric cardiovascular program. The other attending cardiovascular surgeons are thoroughly trained in pediatric cardiovascular surgery. A senior fellow has worked closely with the attending surgeons in a pediatric cardiovascular program.

All house staff members are familiarized with the management of pediatric cardiovascular patients. A pediatric nurse coordinator joined the service to develop training programs for the Cardiovascular Intensive Care Unit nursing staff. She is also responsible for the coordination of parent relations and activities. Parent liaison was recognized as an important aspect of the service. All the above were accomplished with the support of administration and the Departments of Nursing, Pediatrics, and Surgery.

Results

Between September 1986 and October 1987, 30 patients with congenital heart disease underwent open

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heart surgery at The Medical Center of Delaware. The procedures were all performed with the use of cardiopulmonary bypass. Operations included anatomic repair, physiologic correction, and palliative procedures (Table 1). A left thoractomy facilitated surgical exposure in one patient, but median sternotomy was used in all others. Vertical midline skin incision was performed on boys, while a bilateral inframammary incision with subcutaneous flap and subsequent median sternotomy was preferred for cosmetic reasons in girls. Venous drainage was accomplished by right atrial, bicaval, or left femoral vein cannulation. The heart-lung machine included either a membrane or bubble oxygenator. Blood was returned either to the ascending aorta or, less commonly, to the femoral artery. Priming volumes were kept to a minimum to avoid extreme hemodilution. Autologous transfusion was used whenever possible, as were designated or directed blood donations. Core cooling was achieved on cardiopulmonary bypass; myocardial protection was provided with a modified pediatric cardioplegic solution.

Details of Repair

Anatomic correction restores normal or near normal anatomic structures and relations. Such corrections were accomplished in 26 of our patients.

Atrial septal defects may be located in the region of the sinus venosus, fossa ovalis (secundum), atrioventricular canal (primum), or coronary sinus. Direct closure of secundum type atrial septim defects were performed in six patients.

A pericardial patch closure was required in one patient with an essentially common atrium and in another with a large defect to avoid limiting the size of the left atrium. Sinus venous defects with associated partial anomalous pulmonary venous return were corrected in three patients. The right atrium was opened posteriorly and the incision was extended laterally into the superior vena cava to avoid the area of the sinoatrial node. The abnormally draining pulmonary veins were redirected and the defect closed with a pericardial patch. A second pericardial patch was used to expand the caval atrial junction. This avoided narrowing and a resulting superior vena cava syndrome.

One patient had previously undergone patch closure redirection of two of three anomalously draining pulmonary veins; the third pulmonary vein drained high into the superior vena cava at the level of the azygos vein. This patient subsequently developed atrial fibrillation and signs of right ventricular overload, and reoperation was recommended. At reoperation, the previously placed Dacron patch was incised and a pericardial patch was used to close the defect and redirect all anomalously draining veins into the left atrium.

Atrioventricular canal defects may be partial or complete. In the partial form there is a defect involving the primum portion of the atrial septum. A cleft is present in the anterior leaflet of the mitral valve, making this valve tri-leaflet. This abnormal appearing valve may be competent or have varying degrees of regurgitation.

A young patient with a complete atrioventricular canal defect underwent operative repair. A pericardial patch was used to close both the atrial and ventricular components of the defect. The common atrioventricular valve which contained six components, and was repaired, resulted in two competent atrioventricular valves. Again, avoidance of heart block postoperatively was of utmost importance.[1]

TABLE 1

VARIOUS REPAIR TECHNIQUES USED

Anatomic Repair	
ASD	8
ASD - PAPVR	4
VSD	3
AV Canal	2
Subaortic obstruction LVOTO	3
RVOTO - ASD	1
RVOTO - VSD	1
MV Repair & ASD	1
AVR post VSD	1
Tetralogy of Fallot	1
TGA - VSD - PS	1
Physiological Repair	
TGA - ASD	1
TGA - LVOTO - ASD	1
LTGA - SV - PA - ASD	1
Palliative	
PA - Complex CHD - SV	1

KEY

ASD - Atrial septal defect
AV Canal - Atrioventricular canal
AVR - Aortic valve replacement
CHD - Congenital heart disease
LGTA - Corrected transposition of the great arteries
LVOTO - Left ventricular outflow tract obstruction
PA - Pulmonary artresia
PAPVR - Partial anomalous venous return
PS - Pulmonary stenosis
RVOTO - Right ventricular outflow tract obstruction
SV - Single ventricle
TGA - Transposition of the great arteries
VDS - Ventricular septal defect

Another patient with an atrioventricular canal defect had severe mitral valve regurgitation and developed a giant left atrium with compression of the left pulmonary artery and left bronchus.[2] The heart was exposed through a left thoracotomy incision and on cardiopulmonary bypass a left atrial reduction procedure was performed, and left atrioventricular valve was repaired to restore normal function. The defect in the primum portion of the atrial septum was closed.

Ventricular septal defects may be located in the perimembranous, infundibular, inlet, or muscular components of the septum.[3] Primary repair of ventricular septal defects, even in young children, is preferred to palliative procedures such as pulmonary artery banding.[3-6]

We treated two patients with perimembranous defects. These were closed by a transatrial approach using a prosthetic patch. One patient with marked pulmonary hypertension was operated on at one year of age, while the other was operated on electively at five years of age. A third patient, also one year old, had a large inlet type atrioventricular canal ventricular septal defect and systemic levels of pulmonary hypertension. A large prosthetic patch was used to replace the inlet septum. The transatrial approach was used, and particular attention paid to avoidance of injury to the conduction system. The transatrial approach avoids ventriculotomy and its inherent risks.

Obstructive lesions may be present in either the right or the left ventricular outflow tracts. *Left ventricular outflow tract obstruction* occurs at subvalvular, valvular, and supravalvular levels. Severe left ventricular hypertension may occur in subaortic obstruction which may be membranous, muscular, or fibromuscular in type. Two patients in our series had discrete subaortic membranes, but also significant muscular obstruction in the septum beneath that level of the membrane. The membrane was resected and a myotomy and myectomy of the septum was also carried out. This reduced the left ventricular gradient and relieved left ventricular strain. Additionally, both patients had bicuspid aortic valves, and one patient had a narrow aortic route requiring patch augmentation.

In one patient in whom a subaortic gradient of 200 mm Hg was measured preoperatively a diffuse, tunnel-like subvalvular obstruction was present, and a modified Konno procedure was performed. The ascending aorta was opened with a "hockey stick" incision. A vertical ventricular myotomy and myectomy were performed, a second incision was then made in the infundibular portion of the right ventricle, and the ventricular septum was incised parallel to the left ventricular outflow tract and anterior to muscle of Lancisci to avoid the conduction system. The fibromuscular component of the subvalvular stenosis was excised. The incision of the septum was carried to within 1 mm of the aortic annulus. The left ventricular outflow tract was widened by a prosthetic patch sewn in the ventricular septum. The ventriculotomy and the aortotomy were then closed. Heart block occurred in this patient postoperatively, requiring a dual chamber atrioventricular pacemaker. An epicardial pacing wire was placed at the time of surgery and a transvenous atrial active fixation lead was subsequently placed at the time of generator implantation.

Right ventricular outflow tract obstruction may occur at the level of the infundibulum, pulmonary valve, or at the main or branch pulmonary artery levels. One of our patients had severe diffuse muscular and fibromuscular hypertrophy involving the travecular and infundibular portions of the right ventricle. In addition, there were pulmonary valve stenosis and peripheral arterial stenosis, and secundum atrial septal defect. An extensive infundibular resection was carried out through a right ventriculotomy, and a pulmonary valvotomy was performed. The peripheral pulmonary stenosis was corrected and the atrial septal defect was closed. An extensive patch augmentation of the right ventricular outflow tract was performed.

In another child there was severe right ventricular outflow obstruction with obliteration of the right ventricular cavity. In addition, there was a restrictive perimembranous ventricular septal defect which was closed with a patch through the right atrium. An extensive infundibular resection was performed, and the right ventricular outflow tract was expanded with a patch. The patient was weaned from cardiopulmonary bypass, but died of low output syndrome in the early postoperative period.

Congenital abnormalities of the *mitral valve* are present at the supravalvular, valvular, and subvalvular levels, and additional defects are not uncommon. One of our patients had marked mitral valve regurgitation with abnormal valve leaflets and with abnormal subvalvular attachments. An extensive reconstruction of the valve was performed, rendering it competent, and an atrial septal defect was closed.

In the pediatric group, mitral valve replacement, with its inherent risks, is to be avoided. On occasion, prosthetic valve replacements are needed, and the choice of such valves is of utmost importance to pediatric cardiac surgery.[7-9] One patient in our series who had previously undergone closure of a perimembranous type septal defect had progressive aortic valve regurgitation postoperatively. Because of clinical deterioration and the presence of marked cardiomegaly and abnormal hemodynamics, aortic valve replacement was deemed necessary. It was performed using a St. Jude prosthesis.

Tetralogy of Fallot is a congenital cardiac malfor-

mation characterized by underdevelopment of the right ventricular infundibulum with anterior and leftward displacement of the infundibular (conal) septum and parietal extensions.[10] This displacement is associated with right ventricular outflow tract obstruction (pulmonary stenosis) and a malalignment type ventricular septal defect. The defect is usually subaortic and the aorta is biventricular in origin (overriding). The subsequent right ventricular hypertrophy is secondary to the outflow tract obstruction. To repair tetralogy of Fallot, the right ventricle is opened through a longitudinal incision and extensive infundibular resection performed. The ventricular septal defect is closed with a patch which additionally redirects the left ventricular outflow into the aorta. The right ventricular outflow tract is expanded by the use of a prosthetic patch, eliminating the gradient between the right ventricle pulmonary arteries.

In complete *transposition of the great arteries*, the aorta arises entirely or primarily from the right ventricle, and the pulmonary artery entirely or primarily from the left ventricle. The management of these patients depends in large part on the presence of coexisting abnormalities, which include ventricular septal defect, left ventricular outflow tract obstruction, and patent ductus arteriosis. Patients may in addition have tricuspid valve abnormalities, mitral valve abnormalities, coarctation, right aortic arch, right ventricular hypoplasia, and other lesions. In the newborn period, balloon atrial septostomy is frequently necessary to provide mixing at the atrial level and allow survival. Anatomic repair is possible only when the anatomic left ventricle is capable from pressure and volume standpoints of supporting the systemic circulation.

Soon after birth the left ventricular pressure in patients with transposition falls after the pulmonary vascular resistance decreases, unless there are associated lesions to maintain the pressure and volume status of this ventricle. An arterial switch procedure may be performed in neonates with an intact ventricular septum prior to decrease in left ventricular pressure, or in selected patients with favorable anatomy and hemodynamics beyond the newborn period.

One of our patients had transposition of the great arteries, ventricular septal defect, left ventricular outflow obstruction with consequential functional pulmonary stenosis, and atrial septal defect. She had undergone a right Blalock-Taussig shunt (right subclavian artery to right pulmonary artery anastomosis) in her first year of life by one of us (KWM), in order to increase pulmonary blood flow and relieve profound cyanosis. An anatomic type repair was performed at The Medical Center of Delaware as described initially by Dr. Rastelli. The Blalock-Taussig shunt was ligated, and the right ventricle was opened using cardiopulmonary bypass. The ventricular septal defect was closed with a large baffle type patch to redirect right ventricular output into the aorta. The subpulmonary stenosis was closed with sutures and the main pulmonary artery was ligated. A homograft bearing conduit was used to reestablish right ventricular pulmonary artery continuity, and the atrial septal defect was closed directly.

The atrial inversion procedure provides physiologic correction. In such a repair the systemic venus return is directed into the left ventricle and then into the pulmonary artery, while the pulmonary venous return is directed into the left ventricle and then into the pulmonary artery, while the pulmonary venous return is directed to the right ventricle and from there to the aorta. Physiologically appropriate blood, therefore, flows to the lungs and the body. The right ventricle in these cases functions as a systemic ventricle, and the tricuspid valve as the systemic atrial ventricular valve. In the Mustard type repair a trouser shaped patch of pericardium is used to separate the atrium and baffle venous return. In a Senning procedure, atrial tissue is rearranged and used in large part for the construction of these venous channels.

Two patients in our series underwent Mustard repairs. One patient had undergone a balloon atrial septostomy in the newborn period, while the other had adequate mixing through a secundum type atrial septal defect. The patient who underwent a balloon atrial septostomy had, in addition, severe subpulmonary fibromuscular obstruction which caused left ventricular outflow tract obstruction. This obstruction was not discrete and complete resection was not felt to be easily achievable. In addition, the left ventricle pressure was below systemic pressure, and the patient was not considered a candidate for the arterial switch procedure. The subpulmonary obstruction was resected through the pulmonary artery and a Mustard procedure was performed. In both cases, the pulmonary venous atrium was enlarged by the use of a large Gortex patch. In the patient with an intact ventricular septum and no left ventricular outflow tract obstruction, the Mustard procedure was carried out with a cutback of the coronary sinus necessary to avoid obstruction by the inferior vena caval limb of the pericardial patch. A pulmonary venous atrium was also enlarged. Hemodynamically, both patients did well following operation with excellent relief of cyanosis.

The concept of the dispensable right ventricle has advanced surgery for congenital heart disease. Because only a small arteriovenous gradient is necessary to allow blood flow across the pulmonary arterial system, circulatory adequacy may be preserved in the absence of an anatomic right ventricle. One patient in our series had complex congenital heart disease with corrected or levo transposition of the great arteries, a single ventricle, valvular and subvalvular

pulmonary stenosis, and an atrial septal defect. A Fontan type repair was performed. The atrial septal defect was closed and the right atrioventricular valve excluded by the use of a large pericardial patch. The right atrial appendage was attached directly to the transected main pulmonary artery. Therefore, the systemic venous blood drained from the right atrium directly into the pulmonary artery while the pulmonary venous blood drained into the left atrium through the left atrioventricular valve into the functional single ventricle and out into the systemic circuit. This patient had marked relief of cyanosis and improved exercise tolerance postoperatively. The operation provided physiologic correction with orthoterminal connection, so that physiologically appropriate blood flowed to appropriate organs.

Some patients are too sick, or have such complicated intracardiac defects that anatomic or physiologic repairs are not possible as an initial procedure. For these patients, initial palliation is necessary. Procedures such as pulmonary artery banding, atrial septectomy, and systemic to pulmonary artery shunts offer excellent forms of palliation.

One baby in our series had initially undergone a right subclavian to right pulmonary artery shunt as a newborn. Because of immediate shunt failure an ascending aorta to right pulmonary artery shunt with a 4 mm Gortex tube was performed. The baby's condition deteriorated with a marked increase in cyanosis and a hematocrit of 70%. Marked thrombocytopenia, pulmonary atresia[11] and essentially single ventricle were confirmed on cardiac catheterization, and the patient was taken immediately to the cardiovascular operating room. Because of his profound desaturation with associated metabolic acidosis, cardiopulmonary bypass was instituted after a sternotomy was performed in order to resuscitate and support the baby. A 5 mm Gortex tube was placed between the ascending aorta and the right pulmonary artery,[12] which achieved excellent palliation.

Monitoring

After the induction of general endotrachial anesthesia, a peripheral artery is cannulated percutaneously. The radial artery is most commonly chosen and the side of cannulation is determined by the type of operation to be carried out. In patients with previous shunt procedures, the side with a patent subclavian artery is selected. Central venous access is obtained by cannulating the internal jugular vein. A large peripheral venous line is also placed. For more complex procedures, additional monitoring lines are placed, either while the patient is on cardiopulmonary bypass or at the termination of bypass. If left atrial pressure monitoring is planned, a long, custom designed catheter is placed centrally via the right femoral vein. At the inclusion of the operative repair this line is placed across either the foramen ovale or into the left atrium through a small cardiac incision.[13] When left atrial pressure monitoring is no longer required, the catheter can be removed into the venous side and subsequently withdrawn. Additionally, cardiac output catheters are frequently placed directly through the right ventricular outflow tract into the pulmonary artery and into the right atrium, which are useful for monitoring pressures as well as measuring cardiac index. Blood can also be withdrawn directly from the right atrium and the pulmonary artery to determine the presence or absence of a postoperative shunt. Monitoring pulmonary artery pressures frequently is of extreme importance, particularly when weaning patients who preoperatively had severe pulmonary hypertension.

Summary

Thirty patients with congenital heart disease underwent open heart surgical procedures at The Medical Center of Delaware over a 13 month period. There was one postoperative death for an operative mortality rate of 3.3%. Operations resulted in anatomic repair, physiologic correction, or palliation. One child with endocarditis underwent mitral valve replacement for acute mitral regurgitation, and a five year old with metastatic Wilm's tumor underwent excision of intracardiac and intravenous cardiac tumor on cardiopulmonary bypass.

Eighteen additional patients with congenital heart disease underwent closed heart procedures during the same period of time. These included closure of patent ductus arteriosis, repair of coarctation,[14,15] shunt procedures, pacemaker implantation, and pulmonary artery banding.

Five of the patients were premature infants, one of whom weighed only 480 grams at the time of surgery. All five did well postoperatively and were subsequently weaned from ventilators and discharged. Noncardiac procedures such as tracheostomy, resection of extensive neurofibromatosis, pericardial windows, and pectus repair were performed in nine additional patients.

Surgery for congenital heart disease frequently necessitates the use of homograft tissue. For this reason, a cooperative effort has been established to harvest hearts. A homograft storage area has been designated for storage of the grafts after processing, making the tissue available for use in our patients. Cardiac transplantation is an ever increasing concern of pediatric cardiovascular surgeons. In cooperation with colleagues at Columbia Presbyterian Medical Center, a heart was harvested at The Medical Center of Delaware and transported to New York where it was used to replace the heart of a patient followed from his newborn period by one of the authors (KWM).

This two and one half year old boy was born with complete atrioventricular canal and severe pulmonary stenosis. On his first day of life he had undergone a right Blalock-Taussig shunt, performed by the author. He did well until he suffered a viral syndrome and developed severe viral myocarditis with subsequent cardiomyopathy. He underwent orthotopic cardiac transplantation with the Delaware heart and though he did well initially, died suddenly four and one half months following the operation. Circumflex coronary artery occlusion with extensive myocardial infarction was found at post mortem examination. Shortly before his sudden death he was able to visit with the pediatric cardiovascular team at The Medical Center of Delaware.

Conclusion

The surgical management of patients with congenital heart disease comprises a challenging and rewarding part of the work of the cardiovascular surgical team at The Medical Center of Delaware. During the initial year, various procedures in the congenital heart surgeon's armamentarium have been successfully used.

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RECURRENT PERIANAL STREPTOCOCCAL CELLULITIS

Ricardo Castro, M.D.
Jaime Rivera, M.D.

Introduction

Among the most common bacterial infections found in pediatric practice are those produced by streptococci, specifically group A beta-hemolytic streptococci. These organisms cause most bacterial pharyngotonsillitis and are frequently the causative organism in upper respiratory infections in infants (streptococcosis), scarlet fever, pneumonia, bacteremia, septicemia, skin infections (pyoderma), erysipelas, and cellulitis.

However, very little has been written in regard to perianal cellulitis caused by group A beta-hemolytic streptococci.[1-3] We present a case of recurrent nature.

Case Report

A seven year old, afebrile boy, weighing 50 pounds, was seen because of pharyngitis. His throat culture was positive for group A beta-hemolytic streptococci, and he was treated with ten days of oral penicillin V therapy. The repeat throat culture was normal.

A month later he complained of rectal discharge with a sore and itchy bottom. Examination showed a yellow-green discharge coming from the rectum. There was a perianal maculo-erythematous rash and perianal edema tender to the touch. There were no fissures or warts. Perianal culture was positive for group A beta-hemolytic streptococci. Culture from the rectal area was negative for gonococci. Throat culture grew normal flora. The patient was treated with ten days of oral dicloxacillin therapy, after which, reexamination of the perirectal and rectal area was normal. Repeat throat and perianal cultures were negative for group A beta-hemolytic streptococci.

Three weeks later he again showed the same symptoms of perianal rash, tenderness, and edema with rectal discharge and bleeding. The patient was hospitalized and a culture from the perianal area again grew group A beta-hemolytic streptococci. Treatment was with IV ampicillin for 72 hours followed by ten days of oral penicillin V. During the hospitalization a rectosigmoidoscopy and colonoscopy were performed and were normal. CBC, sedimentation rate, ASLO titer, anti D-nase titer, RPR, and bleeding studies were normal. Throat culture showed normal flora, and rectal swabs were negative for gonococci, salmonella, shigella, campylobacter, and rotovirus. After the ten days of oral antibiotics, reexamination was normal. Repeat cultures of the throat and perianal area were negative for group A beta-hemolytic streptococci.

Four weeks later, this child again presented with the same symptoms, but without rectal bleeding. Culture of the perianal area again grew group A beta-hemolytic streptococci. A throat culture was negative. At this time the boy was given parenteral penicillin G benzathine 900,000 units and penicillin G procaine suspension 300,000 units (Bicillin C-R) along with ten days of oral penicillin V therapy. Repeat cultures of the perianal area and throat were negative for group A beta-hemolytic streptococci.

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Dr. Rivera is a pediatric gastroenterologist with a private practice in Newark. Dr. Rivera is also director of Nutrition Support Services at The Medical Center of Delaware.

Three weeks later he again presented with the same symptoms of rectal discharge, sore bottom, and painful defecation without rectal bleeding. The findings were the same: throat culture grew normal flora and a perianal culture was again positive for group A beta-hemolytic streptococci. This time he was treated with parenteral penicillin G benzathine 1,200,000 units (Bicillin L-A) and also with ten days of oral penicillin V. Afterwards, throat and perianal cultures were negative for group A beta-hemolytic streptococci.

A four month old sibling, father, and mother were given throat cultures with the first and last recurrence, and were negative for group A beta-hemolytic streptococci. This child has remained free from illness since his third recurrence.

Discussion

In 1966, Amren, et al, reported the first cases of perianal streptococci cellulitis in ten children.[1] In 1970, Hirschfeld reported six cases in two families.[2] One family included two children and a man, and the other family included three children. In 1985, Spear, et al, described the same condition in 14 children over a ten year period.[3] Of these 29 children, 23 were boys.

Proctitis in two children was reported in 1984 due to group A beta-hemolytic streptococci.[4,5]

The recommended therapy for streptococcal infections has been either penicillin G or V for ten days, or parenteral benzathine penicillin G. In our patient, we initially used dicloxacillin oral for ten days, an antibiotic found effective in the therapy and eradication of group A beta-hemolytic streptococci.[6] With the first recurrence accompanied by rectal bleeding, he was initially treated with three days of IV ampicillin and ten days of oral penicillin V as recommended by Hirschfeld[2] and Spear.[3] During the second recurrence, the therapy used was the one recommended by Amren, ie, parenteral benzathine penicillin, 600,000 units for children under 60 pounds, and ten days of oral penicillin.[1]

With the third recurrence, we decided to give 1,200,000 units of benzathine penicillin G plus ten days of oral penicillin V. Since this therapy he appears cured. Rectal bleeding, which occurred during the first recurrence, has been reported in seven of the total 29 children. Only eight of these children had a recurrence, and none had a second recurrence. Our patient has been, so far, the only reported case who has had three recurrences after complete eradication of the streptococci.

Summary

We have presented the thirteenth case in medical literature and the first case in Delaware of perianal streptococcal cellulitis in a seven year old boy who developed three recurrences of the same disease after being completely treated, and after eradicating the group A beta-hemolytic streptococci each time.

Children who develop perianal rash or rectal discharge should be cultured. The culture should be performed by rotating a sterile swab around the perianal area and then inoculating it on a 5% sheep blood agar plate which is incubated overnight at 37°C. This should then be examined for colony morphology and hemolysis; the bacitracin disc method is used to type streptococci.[7] When using a reference laboratory, the culture request must specify, "Look for Group A beta-hemolytic streptococci," or the swab will be plated in a selective medium hostile to streptococci growth which is routinely used to identify other common enteric pathogens.

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VENOUS RECONSTRUCTION IN VENOUS INSUFFICIENCY SYNDROME

Syde A. Taheri, M.D.

Introduction

Venous insufficiency is a common disorder.[1] Approximately 800,000 new cases of venous insufficiency, 600,000 cases of pulmonary emboli,[2,3] and more than 2,000,000 cases of venous thrombosis[4] occur yearly in the United States. In the last 25 years, considerable progress has been made in the diagnosis and surgical treatment of this condition. Although dermatitis and stasis ulceration with variscosity have been reported for years, myopathy,[5] neuropathy,[6] and energy-depleted calf muscle[7] are new findings which add considerably to better understanding of the pathophysiology of this condition.

Venous insufficiency is attributed either to venous obstruction or to valvular incompetence. Valvular incompetence is considered a result of thrombophlebitis or floppy valve, a condition caused by abnormal collagen in the valve as well as the wall of the vein. In cases of floppy valve,[8] the redundancy of the valve is a result of fragmented collagen. In the postphlebitic condition, the valve is thick and adherent to the wall of the vein due to fibrous deposits and chronic inflammation.

Calf muscle atrophy,[9] as well as neuropathy, are common among patients with longstanding venous insufficiency. Venous insufficiency produces venous hypertension. In normal individuals, the superficial venous blood drains to the deep venous system through perforators. The calf veins drain into the popliteal, superficial common femoral, and iliac vein, and eventually into the vena cava. As a result of valvular incompetency and postphlebitic or floppy venous valves, during standing and exercise blood regurgitates downward and causes capillary venous hypertension.[10] This increases the interstitial space, resulting in decreased cellular nutrition. As a result of venous hypertension and increased venous capacitance, cardiac output drops with the change from the supine to the standing position. However, arterial blood pressure remains the same. The findings explain how vasoconstriction of the arterial capillaries of the calf result in hypoxia and type II muscle atrophy. The neurogenic muscle atrophy found in the muscle biopsies of our patients stimulated us to perform electromyography (EMG). In 21 such patients, EMG abnormalities were found in 18. This muscle atrophy is attributed to chronic anoxia as a result of high compartmental pressure,[11] and an increase in non-oxygenated venous blood. The detrimental effect of venous hypertension and high compartmental pressure results in serious neurofibril smooth muscle atrophy as well as degenerative changes in the mitochondria, such as absence of crestae. Muscle biopsy with P31-NMR spectroscopy has shown that patients with severe venous insufficiency have depleted adenosine triphosphates and adenosine diphosphates, signifying a depletion of energy, as we have reported previously.[12] Although pain, swelling, varicosity and stasis ulceration are common clinical symptons of venous insufficiency, we also consider

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weakness, tiredness, restlessness of the leg, and night cramps all common signs of chronic venous insufficiency, and due to venous hypertension and anoxia resulting from the neuromyopathy. Swelling of the legs is the most common finding in venous insufficiency.[13] Varicosity, dermatitis, and stasis ulceration are late clinical manifestations.

Tests

Besides history and physical examination, non-invasive tests such as plethysmography, Doppler flow velocity as well as photoplethysmography may be used as screening tests for venous insufficiency.[14] We depend heavily on measurement of ambulatory venous pressure as well as venography. Venous pressure is measured by inserting a 19 gauge needle into a vein on the dorsum of the foot, followed by toe raising exercises and/or a continuous venous pressure measurement by means of the DyLES system[15] for four to eight hours. With either technique, although the standing pressure may be high, the range of pressure decrease during exercise is minimal and return time is short. This high venous pressure is transmitted to the calf, causing high compartmental pressure. We feel that a drop of venous pressure of less than 50% of the initial pressure and return time of less than 19 seconds are diagnostically significant.

Ascending and descending venography are the gold standards for diagnosis of this condition.[16] Ascending venography is performed by inserting a 19 gauge needle into a vein on the dorsum of the foot and injecting 100 cc of 60% radiopaque material. While the patient is at an 80° standing position, serial films of the calf, leg, and pelvic veins are obtained. The iliocaval junction must be visualized. This is done by the Valsalva maneuver and placing the patient in supine position with elevation of the leg and calf compression. Descending venography is performed by insertion of a catheter into the cephalic or basilic vein under fluoroscopy screen. This catheter is pushed down to the femoral vein while the patient is at a 90° standing position; with the Valsalva maneuver and injection of 10 cc of 60% radiopaque dye, serial x-rays are taken. In approximately 15% of patients with venous insufficiency, a competent superficial femoral vein is found. If symptoms justify it, the catheter should be passed beyond a competent valve and a second radiopaque injection with the Valsalva maneuver carried out. Transvenous venous pressure measurement during resting and exercise can add considerable information on the hemodynamics of venous insufficiency. During the last eight years, 1,000 cases of ascending and descending venography have been performed by this technique in our institution. There has been no mortality or major complication; the incidence of thrombophlebitis has been approximately 4%.

Electromyography and calf muscle biopsy are two new tests which we also use as part of the work-up in cases of venous insufficiency.

Treatment

The basic treatment for venous insufficiency is reduction of venous and compartmental pressure. Medically this is done by bed rest, elevation, mild diuretic, and elastic stocking. When medical treatment fails and muscle biopsy and EMG are abnormal, surgery should be considered. Surgical treatment includes perforator ligation, excision of the varicosity, skin graft, valvuloplasty,[17] vein transposition, and vein valve transplantation. In venous obstruction or stenosis, vein bypass or angioplasty are the operations of choice in our institution. Upper extremity obstruction is usually bypassed by autogenous vein associated with distal arteriovenous fistula.

During the last seven years, we have had the opportunity to operate on two brachial vein obstructions occurring after mastectomy and radiation. Autogenous leg vein and temporary distal arteriovenous fistula relieved the patients' symptoms. In six patients during the same period, superficial femoral vein obstruction was bypassed with ipsilateral saphenous vein without formation of arteriovenous fistula, with relief of symptoms.

Twelve patients with unilateral left iliocaval occlusion have had a Palma operation without arteriovenous fistula. Six of these are free of symptoms with such bypass. Iliocaval compression syndrome is a common disorder caused by pressure of the right iliac artery against the left iliocaval junction.[18] The patient is screened by exercise plethysmography, a non-invasive technique which requires ten dorsal and plantar flexions of the foot with maximum venous outflow measurement before and after exercise. Patients with symptoms of venous insufficiency and abnormal exercise plethysmography are subjected to venous pressure measurement and venography. Surgical treatment consists of iliocaval angioplasty with autogenous arm vein and retrocaval placement of the right iliac artery after elongation and reconstruction with a segment of hypogastric artery.

Eighteen patients with iliocaval compression syndrome have been surgically corrected in this fashion. The last ten received subcutaneous heparin for three days and Coumadin for three months. Fifteen are doing well, but in three the left iliocaval angioplasty became occluded.

Vein valve transplant has become the operation of choice for intractable venous insufficiency due to valvular incompetence and failure of medical treatment. A two centimeter segment of brachial vein with a competent valve is removed from the arm and inserted into the distal popliteal vein below the knee. Since 1980, 83 patients have received a vein valve transplant for venous insufficiency. Seven years follow-up showed one

occlusion, six venous valve dilatations, and relief of symptoms in 75% of the patients. Since 1986, we routinely cover the segmental valve with autogenous fascia from the leg or arm.

Discussion

Despite the fact that venous insufficiency has been recognized for centuries, the relationship of symptoms and underlying disease has not been fully understood. Varicose veins, stasis pigmentation, and ulceration[19] all have been attributed to venous insufficiency, but today, the discovery of neuromyopathy and energy depletion of the calf muscle should concern the physician as much as the skin manifestations of this condition. When the physician sees a patient with a swollen leg and varicosities, a complete work-up with non-invasive and invasive venous pressure measurement, venography, and muscle biopsy should be included in the work-up.

It is apparent that there is a need for a simple, non-invasive test for early diagnosis. Yearly plethysmography and photoplethysmography seem to be the only available non-invasive tests at the present time. The physician should also bear in mind that pain, restlessness, and swelling may be prodromal signs of venous insufficiency similar to the transient ischemic attack for stroke.

The hemodynamics of venous insufficiency are determined by venous pressure. A decrease of less than 50% in the ambulatory venous pressure is diagnostically significant. Perhaps neuropathy is the earliest complication of this disorder. Our data on muscle biopsy has shown that the majority of our 80 patients showed type II muscle atrophy. Neurogenic myopathy was present in 40% of patients, signifying early degeneration of the nerve, which may indicate myopathy secondary to peripheral nerve impairment. Therefore, early recognition of venous insufficiency is essential to prevent the disabling sequelea of neuromyopathy. Finally, we should consider the effects of chronic oxygen-free radicals generated by longstanding anoxia of the calf muscle. Swelling, muscle atrophy, and abnormal mitochondria findings could be attributed to toxic oxygen-free radicals. More clinical and laboratory study is required to determine the relationship of venous insufficiency and oxygen-free radicals.

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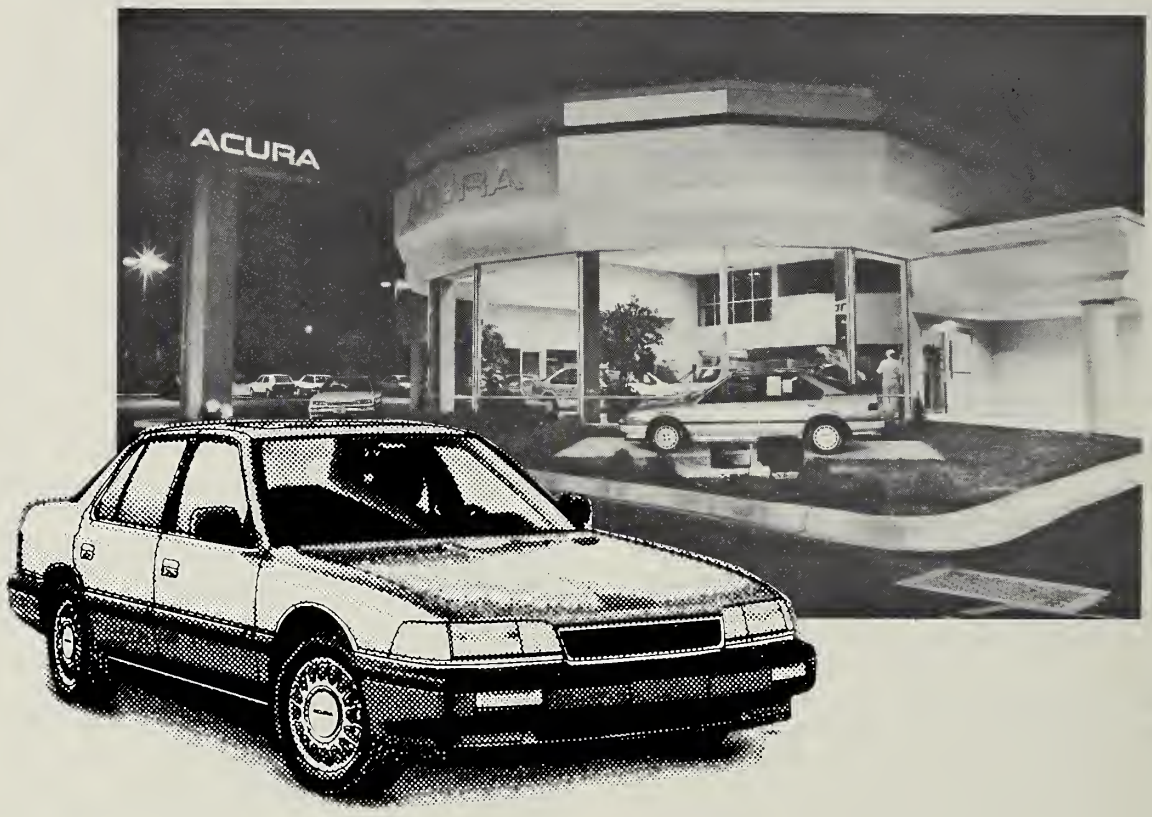

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Special Report

HOUSE OF REPRESENTATIVES
134TH GENERAL ASSEMBLY
HOUSE CONCURRENT RESOLUTION NO. 121
SPONSOR: Rep. Maroney; Sen. Minner
MARCH 24, 1988

COMMEMORATING DR. MARGARET I. HANDY FOR A LIFETIME OF LANDMARK ACHIEVEMENTS AND DEVOTION TO CHILDREN AND MEDICINE AS SHE IS INDUCTED INTO THE HALL OF FAME OF DELAWARE WOMEN.

WHEREAS, Dr. Margaret I. Handy has long championed the medical care for the children in our State; and

WHEREAS, born in Smyrna, Delaware in 1889 she was graduated from Johns Hopkins Medical School to become the first native-born female physician and our State's first pediatrician; and

WHEREAS, Dr. Handy's uncompromising devotion to the plight of children led her to establish a children's ward at People's Settlement in Wilmington, where she served as physician, nurse, janitor and lullaby singer; and

WHEREAS, Dr. Handy subsequently established a pediatric clinic in the Delaware Hospital in Wilmington, from which her influence spread rapidly through all aspects of child care, development and welfare throughout the State; and

WHEREAS, her energy was boundless and her determination to promote the highest standards of care for all children led to her recognition as one of the most outstanding women in America; and

WHEREAS, Dr. Handy became renown as a crusader for improved care for premature babies and established a mother's milk bank for premature babies, subsequently becoming Chief of Pediatrics at the Delaware Hospital in 1921; and

WHEREAS, she will be remembered by many as the pure image of shining intelligence in her Andrew Wyeth portrait, her face strong and her medical bag prominent; and

WHEREAS, as a teacher, Dr. Handy demanded and received the best from her students, always encouraging them to study harder and strive to reach the top of their profession; and

WHEREAS, Dr. Handy's achievements earned her many honors, including the Elizabeth Blackwell Citation honoring women doctors and the 1953 Josiah Marvel Cup as the Most Distinguished Delaware Citizen of the Year; and

WHEREAS, Dr. Handy died in 1977 but left behind a healthy legacy of Delaware infants and a benchmark career worthy of emulation; and

WHEREAS, the mark she left on her native Delaware and the quality care she provided thousands of residents says more than any award, any eulogy ever could but still we wish to bestow an honor upon her in the form of a Hall of Fame title.

NOW THEREFORE:

BE IT RESOLVED by the House of Representatives of the 134th General Assembly of the State of Delaware, the Senate concurring therein, that we hereby do resolve to commemorate Dr. Margaret I. Handy for a lifetime of medical achievements as she is inducted into the Hall of Fame for Delaware Women March 24, 1988.

BE IT FURTHER RESOLVED that a suitably prepared copy of this resolution be forwarded to the Medical Society of Delaware.

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Medical Ethics

The Statement on Physician Advertising, and Ethical Guidelines for Professional Advertising, which follow, were adopted by the Board of Trustees of the Medical Society of Delaware on June 9, 1988.

STATEMENT ON PHYSICIAN ADVERTISING

The Committee on Ethics of the Medical Society of Delaware has been asked by several physicians to outline an acceptable stance on physician advertising. Advertising by physicians is now an accepted fact of life, although for many it stirs up rancor and distaste. It is necessary to remember that advertising is legal and that attempts to restrict advertising can be countered with restraint-of-trade and freedom of speech concerns. To advertise or not must therefore be an individual decision.

Physicians who advertise have the responsibility to be sure that their ads are accurate and not misleading; good taste is harder to define but just as desirable. Some examples of recent advertising imply that the services being promoted can only be obtained through the advertisers and then only by going to those doctors can topnotch and highest quality services be obtained. The Ethics Committee urges physicians who choose to advertise to be careful of the wording so that other physicians do not feel libeled. Also, the physician who makes efficacy claims through advertising may be increasing his/her risks of liability and problems with the Federal Trade Commission.

The *Delaware Medical Journal* now requires that advertising for medical services, including laboratory and special procedures, indicate the responsible physicians, in contradistinction to advertisements in the past which omitted physician owners' names. Although the *Journal's* editorial policy may not reflect an ethical guideline, it certainly indicates the medical community's changing attitudes toward professional advertising.

How advertisements are distributed raises more difficult questions. Any method which solicits patients directly or indirectly, especially patients of other physicians, is likely not only to arouse antagonism among the advertiser's peers but if not carefully controlled may be questioned ethically. For example, the committee would look unfavorably on passing out business cards among patients in a coronary care unit (unethical and distasteful; very unprofessional). "Ambulance chasing" has always been considered unethical as would contacting the family of an injured football player to offer one's medical services. Placing advertisements in the office of a physician in the same field could be interpreted as unethical solicitation. This would be especially true if patients are urged to switch doctors in the midst of a treatment course. On the other hand, second opinions are an acceptable method for a patient or his insurance company to be fully informed of the options in a particular situation. In a recent survey of Delaware physicians, there was no consensus on whether the physician being asked to render a second opinion should or could ethically accept the patient for treatment because to deny this would seem to unduly restrict the patient's free choice of physicians. In spite of that, many physicians do not feel ethically comfortable accepting for treatment a patient scheduled for a second opinion.

Efforts to restrict choice of a physician, except when previously contracted as in an HMO or by a compa-

ny for an industrial accident, can be questioned. Even in the HMO and in industrial accident cases, most patients can still choose their own physician, although payment for such services may not be approved by the contracting body. In the absence of such a contract, it is usually in the patient's best interest to be offered a choice among qualified physicians. It is considered unethical to offer fiscal incentives such as splitting fees or providing favors to anyone making a referral.

It is acceptable to refer a patient to a facility or service in which a physician has a fiscal interest, if the patient is informed of the physician's involvement. Usually it is best to give the patient a choice, if one exists, while mentioning the financial or other interest the referring physician has in such a "service." Giving the patient two choices reduces any question of unethical behavior.

The committee is willing to advise and counsel but is not a disciplinary committee. Discipline is the function of the County Peer Review Committees, and, if appropriate, the Board of Trustees of the State Society or the Board of Medical Practice.

While open competition to provide better care can be an important factor in medical progress, good science and optimum patient care should also be promoted through persuasion and education.

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ETHICAL GUIDELINES FOR PROFESSIONAL ADVERTISING

A. A physician should not, on behalf of himself, or his associates, or his professional organization use or participate in the use of any form of communication containing a materially false, fraudulent, deceptive, or unfair statement or claim.

B. A physician may publish or broadcast information concerning his practice in print media or over television or radio in the geographic area or areas in which the physician maintains offices or in which a significant part of the physician's patients reside. The information which the physician presents should comply with A. above. Advertisements might include but are not limited to the following:
   1. Name, including the names of associates, addresses and telephone numbers;
   2. One or more fields of medicine in which the physician practices;
   3. One or more specialties in which the physician is board certified;
   4. Date and place of birth;
   5. Schools attended, with dates of graduation, degrees and other scholastic distinctions;
   6. Authorship of medical articles;
   7. Medical teaching positions;
   8. Membership, offices, and committee assignments in medical associations;
   9. Membership and offices in medical societies;
   10. Membership in scientific, technical and professional associations and societies;
   11. Foreign language ability;
   12. Office and telephone answering service hours;
   13. Fee for initial consultation;
   14. Availability upon request of a written schedule of fees.

C. It is suggested that if the advertisement is communicated to the public over television or radio, it should be prerecorded and approved for broadcast by the physician, and a recording of the actual transmission retained.

D. If a physician advertises a fee for a service, the physician must render that service for no more than the fee advertised.

E. These guidelines do not apply to the identification of a physician in materials which are not published for the purpose of advertising a professional service, including but not limited to:
   1. Political advertisements when his professional status is germane to the political campaign or to a political issue.
   2. Routine reports and announcements of a bona fide business, civic, professional or political organization in which he serves as a director or officer.
   3. Medical documents prepared by him.
   4. Medical textbooks, treatises, and other medical publications, and in advertisements, thereof.

F. A physician shall not compensate or give anything of value to representatives of the press, radio or television, or other communication medium in anticipation of or in return for professional publicity in a news item.

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2. Because nizatidine is excreted primarily by the kidney, dosage should be reduced in patients with moderate to severe renal insufficiency.

3. Pharmacokinetic studies in patients with hepatorenal syndrome have not been done. Part of the dose of nizatidine is metabolized in the liver. In patients with normal renal function and uncomplicated hepatic dysfunction, the disposition of nizatidine is similar to that in normal subjects.

Laboratory Tests—False-positive tests for urobilinogen with Multistix® may occur during therapy with nizatidine.

Drug Interactions—No interactions have been observed between Axid and theophylline, chlordiazepoxide, lorazepam, lidocaine, phenytoin, and warfarin. Axid does not inhibit the cytochrome P-450-linked drug-metabolizing enzyme system; therefore, drug interactions mediated by inhibition of hepatic metabolism are not expected to occur. In patients given very high doses (3,900 mg) of aspirin daily, increases in serum salicylate levels were seen when nizatidine, 150 mg b.i.d., was administered concurrently.

Carcinogenesis, Mutagenesis, Impairment of Fertility—A two-year oral carcinogenicity study in rats with doses as high as 500 mg/kg/day (about 80 times the recommended daily therapeutic dose) showed no evidence of a carcinogenic effect. There was a dose related increase in the density of enterochromaffin-like (ECL) cells in the gastric oxyntic mucosa. In a two-year study in mice, there was no evidence of a carcinogenic effect in male mice, although hyperplastic nodules of the liver were increased in the high dose males compared to placebo. Female mice given the high dose of Axid (2,000 mg/kg/day, about 330 times the human dose) showed marginally statistically significant increases in hepatic carcinoma and hepatic nodular hyperplasia with no numerical increase seen in any of the other dose groups. The rate of hepatic carcinoma in the high dose animals was within the historical control limits seen for the strain of mice used. The female mice were given a dose larger than the maximum tolerated dose, as indicated by excessive (30%) weight decrement compared to concurrent controls, and evidence of mild liver injury (transaminase elevations). The occurrence of a marginal finding at high dose only in animals given an excessive, and somewhat hepatotoxic dose, with no evidence of a carcinogenic effect in rats, male mice, and female mice (given up to 360 mg/kg/day, about 60 times the human dose), and a negative mutagenicity battery is not considered evidence of a carcinogenic potential for Axid.

Axid was not mutagenic in a battery of tests performed to evaluate its potential genetic toxicity, including bacterial mutation tests, unscheduled DNA synthesis, sister chromatid exchange, and the mouse lymphoma assay.

In a two-generation, perinatal and postnatal, fertility study in rats, doses of nizatidine up to 650 mg/kg/day produced no adverse effects on the reproductive performance of parental animals or their progeny.

Pregnancy—Teratogenic Effects—Pregnancy Category C—Oral reproduction studies in rats at doses up to 300 times the human dose, and in Dutch Belted rabbits at doses up to 55 times the human dose, revealed no evidence of impaired fertility or teratogenic effect, but, at a dose equivalent to 300 times the human dose, treated rabbits had abortions, decreased number of live fetuses, and depressed fetal weights. On intravenous administration to pregnant New Zealand White rabbits, nizatidine at 20 mg/kg produced cardiac enlargement, coarctation of the aortic arch, and cutaneous edema in one fetus and at 50 mg/kg if produced ventricular anomaly, distended abdomen, spina bifida, hydrocephaly, and enlarged heart in one fetus. There are, however, no adequate and well-controlled studies in pregnant women. It is also not known whether nizatidine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Nizatidine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers—Nizatidine is secreted and concentrated in the milk of lactating rats. Pups reared by treated lactating rats had depressed growth rates. Although no studies have been conducted in lactating women, nizatidine is assumed to be secreted in human milk, and caution should be exercised when nizatidine is administered to nursing mothers.

Pediatric Use—Safety and effectiveness in children have not been established.

Use in Elderly Patients—Ulcer healing rates in elderly patients are similar to those in younger age groups. The incidence rates of adverse events and laboratory test abnormalities are also similar to those seen in other age groups. Age alone may not be an important factor in the disposition of nizatidine. Elderly patients may have reduced renal function.

Adverse Reactions: Clinical trials of nizatidine included almost 5,000 patients given nizatidine in studies of varying durations. Oomestic placebo-controlled trials included over 1,900 patients given nizatidine and over 1,300 given placebo. Among the more common adverse events in the domestic placebo-controlled trials, sweating (1% vs 0.2%), urticaria (0.5% vs <0.01%), and somnolence (2.4% vs 1.3%) were significantly more common in the nizatidine group. A variety of less common events was also reported; if was not possible to determine whether these were caused by nizatidine.

Hepatic—Hepatocellular injury, evidenced by elevated liver enzyme tes (SGOT [AST], SGPT [ALT], or alkaline phosphatase), occurred in some patien possibly or probably related to nizatidine. In some cases, there was marke elevation of SGOT, SGPT enzymes (greater than 500 IU/L), and in a sing instance, SGPT was greater than 2,000 IU/L. The overall rate of occurrences elevated liver enzymes and elevations to three times the upper limit of norm however, did not significantly differ from the rate of liver enzyme abnormalities placebo-treated patients. All abnormalities were reversible after discontinuatic of Axid.

Cardiovascular—In clinical pharmacology studies, short episodes asymptomatic ventricular tachycardia occurred in two individuals administer Axid and in three untreated subjects.

Endocrine—Clinical pharmacology studies and controlled clinical tria showed no evidence of antiandrogenic activity due to Axid. Impotence a decreased libido were reported with equal frequency by patients who receiv Axid and by those given placebo. Rare reports of gynecomastia occurred.

Hematologic—Fatal thrombocytopenia was reported in a patient who w treated with Axid and another H_2-receptor antagonist. On previous occasion this patient had experienced thrombocytopenia while taking other drugs.

Integumental—Sweating and urticaria were reported significantly mo frequently in nizatidine than in placebo patients. Rash and exfoliative dermatit were also reported.

Other—Hyperuricemia unassociated with gout or nephrolithiasis wa reported.

Overdosage: There is little clinical experience with overdosage of Axid humans. If overdosage occurs, use of activated charcoal, emesis, or lavag should be considered along with clinical monitoring and supportive therap Renal dialysis for four to six hours increased plasma clearance by approximate 84%.

Test animals that received large doses of nizatidine have exhibited cholinerg type effects, including lacrimation, salivation, emesis, miosis, and diarrhe Single oral doses of 800 mg/kg in dogs and of 1,200 mg/kg in monkeys were n lethal. Intravenous LD_{50} values in the rat and mouse were 301 mg/kg and 23 mg/kg respectively.

PV 2091 AMP [04128

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Indianapolis, Indiana
46285

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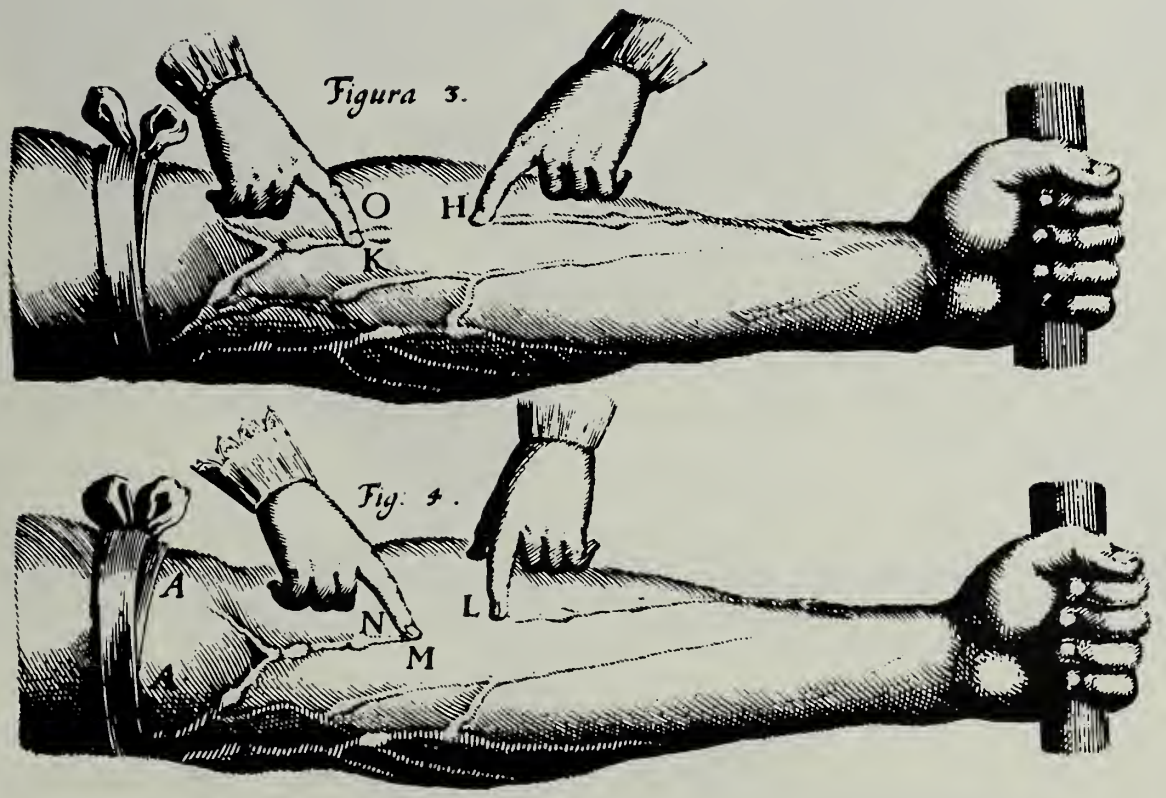
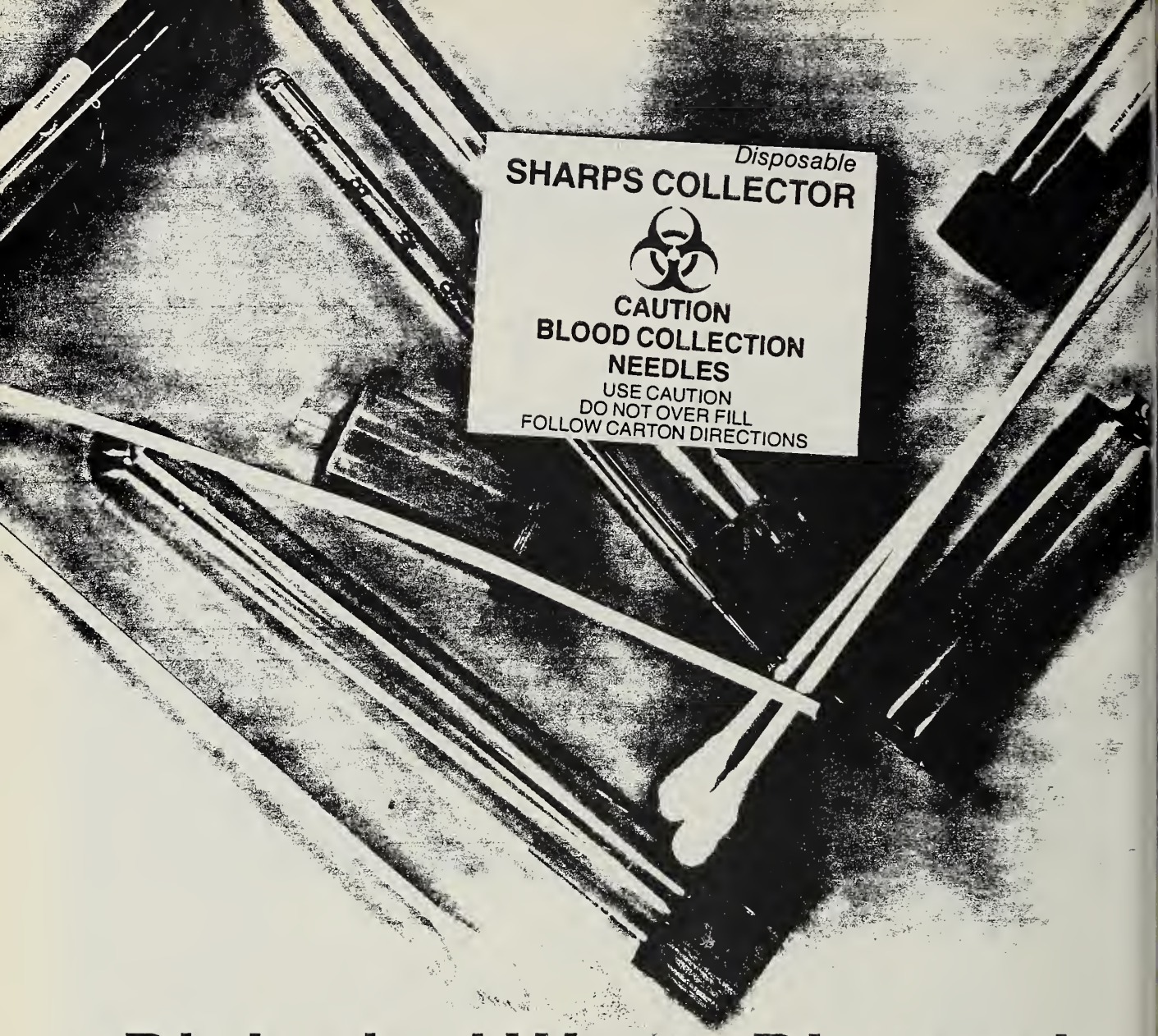
In Black and White

Dennis R. Witmer, M.D. Photographic Editor



Illustrations from William Harvey's *De Motu Cordis and Sanquinis in animalibus*, published in 1639. Harvey's discovery of the circulation of the blood is usually considered the most important single medical work ever published.



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Deaths

F.B. LANE HAINES, M.D.

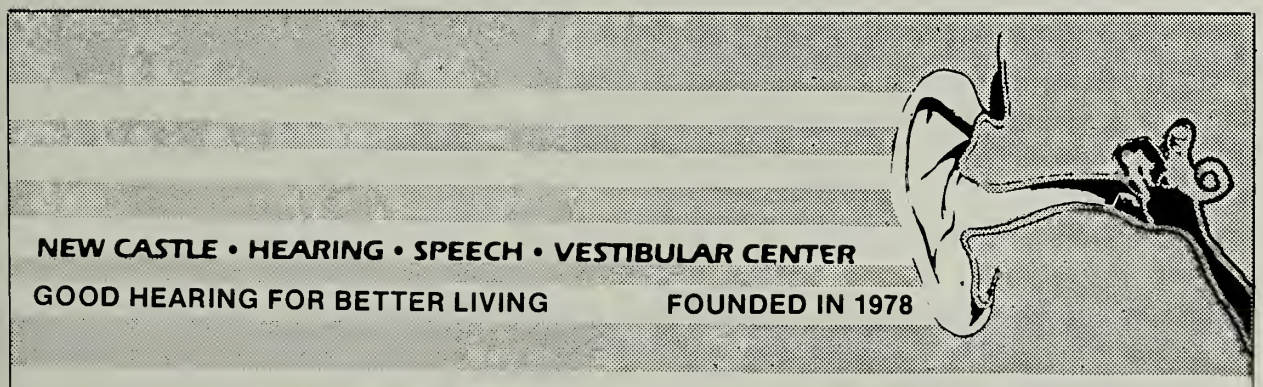
F.B. Lane Haines, M.D., of Felton, died of a heart attack June 17, 1988, at Kent General Hospital. He was 78.

Dr. Haines was a graduate of Westtown School, Swarthmore College, and Temple Medical School, from which he graduated in 1940. He practiced medicine with his parents, Dr. Willits and Florence Haines in Ocean City, New Jersey, later serving his residency in anesthesia at Philadelphia General Hospital. He practiced anesthesiology at Cooper Hospital in Camden, New Jersey, before coming to Kent General Hospital in 1959 to serve as their first anesthesiologist.

In 1970, Dr. Haines founded the F.B. Lane Haines School of Anesthesiology at Kent General Hospital.

Upon retiring from Kent General in 1977, Dr. Haines began a general practice in Kent County, which continued until the time of his death. He was also a Federal Aviation Administration examiner in Delaware and New Jersey, a position he held more than 40 years.

Dr. Haines was a member of the American Medical Association, the Medical Society of Delaware, and the Kent County Medical Society.



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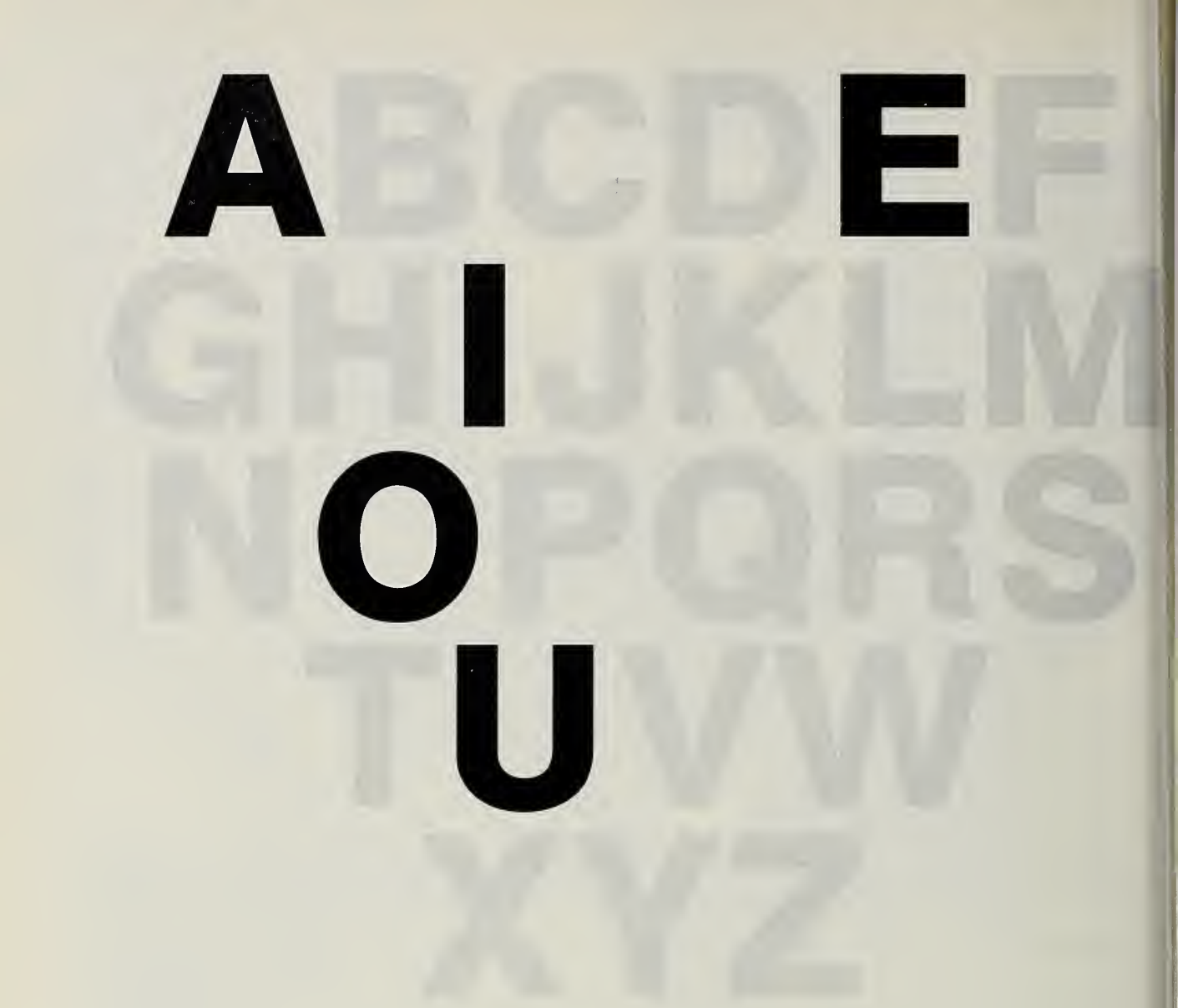

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Editorials

Members of the Medical Society of Delaware are invited to submit material. Preferred length is approximately 250-500 words. For further information contact the Journal office, 658-3957.

PRIMARY CARE: NEW PATTERNS OF TRAINING

There is a great need in this country now for primary care physicians. Theoretically, this need is being met by the existing training programs for internists, pediatricians, and family physicians. But the effort is not adequate. Both internal medicine and pediatric programs are planned too heavily toward care of very sick hospitalized patients. The urgent need is for physicians who are trained primarily to provide truly comprehensive care of ambulatory patients, in addition to caring for those who are hospitalized.

We cannot expect patterns of training to change overnight. But we can start thinking and planning for a future when internal medicine, pediatrics, and family practice will unite their efforts and offer a combined primary care residency program. Then the internal medicine and pediatric departments can each offer an additional, much reduced training program for those who will become consulting physicians in their departments.

David Platt, M.D.

THERAPY OF PEPTIC ULCER DISEASE: THE DOCTOR'S DILEMMA

The therapy of peptic ulcer disease was reasonably uncomplicated prior to 1976. Detailed diets, usually of the bland, ie, tasteless, variety were offered, and milk, cream, and liquid antacid programs were strenuously outlined. Since many patients had great difficulty following these rigid therapies, an element of guilt was added to their abdominal discomfort. The introduction of cimetidine, the first clinically offered histamine-2 receptor antagonist, abruptly changed the therapeutic approach. Cimetidine was capable of inhibiting basal acid output by 90% and food-stimulated acid by 70%, approximating the effects of truncal vagotomy. More than 90% of patients with duodenal ulcers were healed after eight weeks of therapy with cimetidine. Very few dietary restrictions were needed, merely the avoidance of caffeine-containing beverages and alcohol.

An interesting offshoot of cimetidine therapy was the opportunity to conduct randomized trials comparing antacids, given one and three hours after meals and at bedtime with the H-2 receptor antagonist. These studies showed for the first time that correctly administered liquid antacids are as effective as cimetidine for ulcer healing.

Since outpatient compliance programs recommending seven daily doses of liquid antacid result in predictably poor compliance, most clinicians understandably prescribed cimetidine for peptic ulcers. The simplicity of this approach was complicated by the introduction of ranitidine, the second histamine-2 receptor antagonist, which has a somewhat longer duration of action, and thus can be given twice daily, and has fewer neurologic effects in older patients who have renal or hepatic disorders. The major benefit, however, is its lack of significant inhibition of cytochrome P-450, the hepatic enzyme responsible for drug metabolism. The decreased metabolism of warfarin, theophyllin, ben-

zodiazepam, and other drugs when given in conjunction with cimetidine does not occur with ranitidine. The peptic ulcer healing rate for ranitidine is, however, no different from the seven dose antacid program or cimetidine.

After ranitidine was introduced, the clinician was faced with a choice between two excellent drugs having equal therapeutic effects and some differences which, for many patients, are unimportant. The significance of nocturnal acid secretion was recognized by the introduction of single dose bedtime therapy, 800 mg of cimetidine or 300 mg of ranitidine, each producing the same rate of healing.

One might think that the availability of two drugs having high ulcer healing rates would be sufficient, but the introduction of sucralfate, a sulfated sucrose, changed the decision-making process even further, since this drug has no effect on acid secretion. Sucralfate appears to bind to exposed protein in the ulcer base, thus forming a protective covering against acid, bile, and pepsin. The drug is minimally absorbed and has no known serious side-effects. Sucralfate is a rather large tablet, which some patients have difficulty swallowing, and the need to take the medication four times daily, preferably 30-60 minutes before meals so it does not bind to food protein, may be inconvenient. The healing rate with sucralfate approximates that with the other available therapies.

The introduction of famotidine has not clarified the drug selection dilemma, since this third histamine-2 receptor antagonist can also be given nightly, has a somewhat longer duration of action than the other acid suppressants, but appears to induce the same rate of healing.

It would not be unreasonable to ask for a moratorium on new ulcer therapies, but this is not to be the case. Clinical trials suggest that certain prostaglandin compounds can enhance mucosal defenses and heal peptic ulcers, while other studies suggest that omeprazole, a drug which more effectively inhibits acid secretion, has great promise. In addition, the demonstration of an organism, C. Pylori, in antral mucosa suggests a bacterial role in some non-healing or recurring ulcers. Bismuth subsalicylate and several antibiotics have been useful in eradicating the organism, but the clinical significance of C. Pylori is presently unclear.

Another unsolved therapeutic problem is deciding which one of the available drugs is best able to protect the mucosa against the ulcerogenic potential of NSAIDs, commonly given to patients with chronic rheumatic disorders.

In 1975, the major decision was which liquid antacid to use. At this point we have many options, all of which are equally effective for peptic ulcer. The choice between H-2 receptor antagonist or sucralfate is probably unimportant for most patients but ranitidine, famotidine, or sucralfate seem better choices than cimetidine for patients taking other medications with a narrow therapeutic range.

The possible introduction of omeprazole, prostaglandins, and perhaps other drugs will not make our decision-making any easier, but who would prefer to return to the Sippy Diet?

Harris R. Clearfield, M.D.

Dr. Clearfield is the director of the Division of Gastroenterology, and professor of Medicine at Hahnemann University, Philadelphia.

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WHERE THEY STAND: BUSH AND DUKAKIS ON HEALTH AND RELATED TOPICS

I. AIDS

1. Do you favor testing for AIDS for all citizens?

Bush: (note the candidate presented the following statement in response to Questions 1-6 on AIDS issues). We must do all we can do to stop the spread of AIDS in this country. We must look for innovative solutions to this staggering problem. But money alone won't stop AIDS. Those at high risk must be educated on how to avoid contracting the disease. The only guaranteed way to halt the spread of AIDS, given what we know now, is a change of behavior.

The issue of testing raises some difficult and troublesome questions for me. It puts in conflict the need for more information and knowledge to benefit the majority versus our basic Constitutional right to privacy. And it is the responsibility of the political leadership of the country to decide among these competing principles.

Ultimately, we must protect those who do not have the disease. Thus, we have made the decision that there must be more testing. We are encouraging states to offer routine testing for those who seek marriage licenses and for those who visit sexually transmitted disease or drug abuse clinics. We are also encouraging states to require routine testing in state and local prisons.

Of course, any mention of testing must be hurriedly followed by the word, "confidentiality." If society feels compelled, in some circumstances, to test its citizens, then it is absolutely imperative that those records are kept appropriately confidential. It is also imperative that help be available to those who test positive. We need testing, but only accompanied by guarantees that everyone is treated fairly.

I feel deeply for parents on both sides of this issue. I understand the concerns of parents allowing school age students who either test positive for AIDS or who have AIDS to stay in the classroom. Parents have a legitimate right to demand that their children be educated in a healthy environment. At the same time, the parents of children who either have AIDS or who have tested positive for the AIDS virus have a real concern that their children not be unnecessarily isolated from a normal social setting. Although this is a highly emotional issue, we must make our decision based on the best current evidence that the medical profession has to offer. Based on what the doctors tell us, I believe that these children should be allowed to stay in the classroom, on the condition that proper safeguards are taken.

Dukakis: No.

2. Should such testing be voluntary or mandatory?

Bush: See comment to question 1.

Dukakis: Voluntary. I do not favor AIDS testing for the entire population, only for those who seek it. We should, however, encourage voluntary testing for those in high risk groups.

3. Should there be testing only of specific groups?

Bush: See comment to question 1.

Dukakis: Yes. I favor mandatory testing only in two cases: in the military and in keeping with the traditional authority of the Immigration and Naturalization Service to test immigrants coming from areas of the world with high incidences of communicable dis-

ease. But, even in this latter case, exceptions should be made on humanitarian grounds (ie, to allow persons with AIDS to come to the United States for treatment, or to visit relatives).

4. Do you favor a federal or state standard of confidentiality for individuals presenting themselves for testing and counseling?

Bush: See comment to question 1.

5. Should school age children who either test positive for AIDS virus or have AIDS be allowed to stay in the classroom if they do not exhibit anti-social behavior such as biting?

Bush: See comment to question 1.

Dukakis: Yes.

6. How would you balance the competing interests of the general population and AIDS victims to protect their respective rights?

Bush: See comment to question 1.

Dukakis: I do not believe that the interests of the general population and the interests of persons with AIDS are mutually exclusive. It is in everyone's best interest that we maintain our constitutional rights by keeping AIDS testing confidential. And as our nation's most serious public health threat, it is in all of our interests to prevent its further spread, find a cure, develop a vaccine, and provide compassionate care for people with AIDS.

II. MEDICARE FUNDING

7. Would you support increasing Medicare beneficiary premiums and deductibles for the elderly with higher incomes as one method of resolving expected future Medicare funding short-falls?

Bush: I am committed to ensuring that our country has an effective health care system; and as President, I will continue the federal government's vital role in providing care for the truly needy. As the population ages, Medicare spending will undoubtedly rise, because our trust to provide for seniors' health is clear. I am personally committed to living up to this trust. However, we now spend 11% of our GNP on medical care, more than any other industrialized country. I am seriously concerned about the rise in medical costs throughout the economy. We must encourage greater efficiency in Medicare so that funds allocated for Medicare are used to care for seniors, not to pay for overhead. We must find ways of covering the costs of health care--without sacrificing its quality.

The immediate threat to health care for the elderly is the fact that Medicare Trust Funds are likely to go bankrupt within the next ten years. We must address this problem with a bipartisan solution before it is too late. In the meantime, we should exempt Social Security from budget cuts and avoid means-testing it.

I have supported the Administration's effort to slow the increase in hospital costs through the institution of the Prospective Payment System. We also need to *encourage* physicians to participate in Medicare. I am, however, against mandating assignment. I am skeptical of regulatory schemes that could have the unintended effect of lowering the quality of health care.

Dukakis: No.

8. Would you support a program where the federal government would issue a voucher or coupon to the elderly so they could purchase their own health insurance in the private sector?

Bush: See comment to question 7.

Dukakis: No.

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III. TOBACCO

9. Do you support efforts to ban smoking on commercial airline carriers?

Bush: There is now a ban on smoking on commercial airline carriers for flights under two hours. As President I will uphold and enforce the law.

Dukakis: Yes.

10. What is your stand on the issue of banning cigarette advertising?

Bush: Although I do not smoke and do not encourage others to do so, I am concerned that banning advertisement is an unconstitutional abridgement of our fundamental right to free speech.

Dukakis: Although the federal government should work to decrease the use of cigarettes in our society, an outright ban on cigarette advertising raises troubling questions about first amendment rights.

IV. PROFESSIONAL LIABILITY REFORM

11. Do you favor the federal government extending financial incentive to states that enact minimum tort reform measures?

Bush: Medical care and the availability of necessary pharmaceuticals are threatened by the litigation explosion, particularly in such areas as obstetrics and neurosurgery. Tort reform is urgently needed to address this problem. The states have the primary role in reforming tort law. However, I do favor certain reforms that restore fairness and balance the nation's tort system. I believe we must consider such important reforms as:

> Restoration of fault as the standard of recovery of damages, since liability in the absence of wrongdoing directly contributes to the excessive effect of current tort law; elimination of the joint and several liability rule under which minimally involved defendants can be forced to pay 100% of a plaintiff's claim; and expanded use of alternative dispute mechanisms such as binding arbitration and mediation to encourage early resolution of disputes without burdening the court system.

Dukakis: Although there are provisions of the tax code that I would eventually wish to change, I believe we need a period of stability in the tax system. It is disruptive and burdensome for everyone when there are major changes in the tax code almost every year, as there have been for more than a decade.

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However, I favor creation of a national model of liability reform which states should be encouraged to follow. Uniformity and predictability in these matters will do much to ease many of the problems associated with professional liability.

As Governor, I supported the Massachusetts Medical Malpractice Reform Act of 1986 which set a $500,000 limit on the amount which a jury can award for non-economic damages, ie, pain and suffering. This cap is intended to strike a balance between the real needs of an injured patient and the very legitimate problems occurring in the medical community as a result of the increase in the number and size of malpractice claims. The law provides that in extraordinary circumstances, a jury may exceed the $500,000 limit. There is no limit on the amount recoverable for economic damages.

12. What is your stand on a uniform federal law on medical malpractice claims?

Bush: See comment to question 11.

Dukakis: Rising medical malpractice insurance premiums pose a serious threat to both physicians and patients and to the availability of quality, affordable health care.

As I pointed out in my comments on question 11, Massachusetts has enacted medical malpractice reform legislation which caps liability awards for malpractice pain and suffering at $500,000 and provides graduated limits on attorneys' contingent fees at 40% for judgments up to $150,000 and 25% for judgments over $500,000. These reforms have contributed substantially to stabilizing malpractice premiums, while at the same time, ensuring reasonable compensation to victims and preserving access to our legal system and competent attorneys.

V. FAMILY MEDICAL LEAVE

13. What employment policies, if any, should be federally mandated to deal with family medical leave issues?

Bush: I believe that the federal government has an obligation to encourage private industry to comply with

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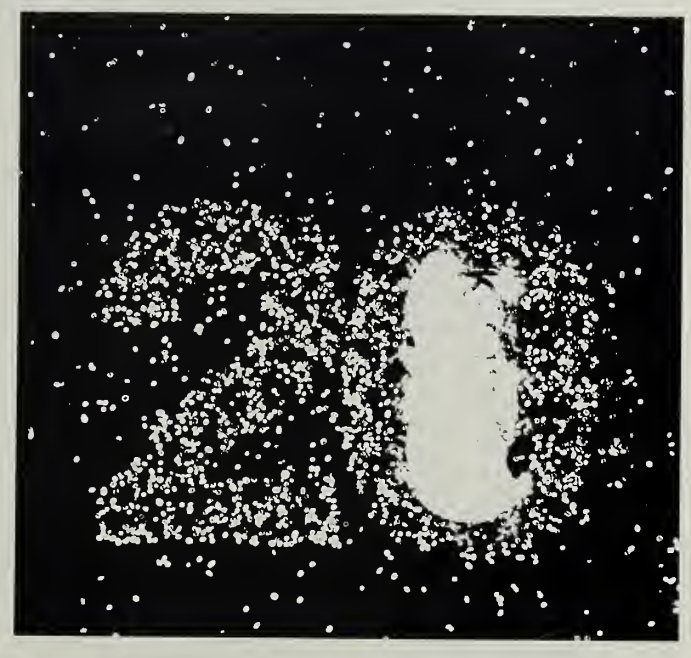
current civil rights legislation as it pertains to the health of the American citizen. However, I am skeptical of any attempt to use federal regulations to manage the details of issues such as family medical leave. Such regulations are invariably inefficient, unnecessarily increase the cost of health care to the consumer, and encumber private industry with additional costs which cut into American competitiveness.

While the federal government should not be in the business of imposing standards, it can provide leadership and research in determining policies on family medical leave. The states can lead by implementing the highest quality standards that are responsive to the special needs of their own areas. And as with the states, I hope to encourage the private sector to take the lead as well.

Dukakis: I support minimum federal standards for unpaid leaves of absence for employees faced with medical disability or parenting responsibilities arising out of birth, adoption, or serious illness. Employees on such leaves should be protected against the loss of previous-



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3. The use of potassium salts in patients receiving diuretics for uncomplicated essential hypertension is often unnecessary when such patients have a normal dietary pattern. Serum potassium should be checked periodically, however, and if hypokalemia occurs, dietary supplementation with potassium-containing foods may be adequate to control milder cases. In more severe cases supplementation with potassium salts may be indicated.

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Wax-matrix potassium chloride preparations have produced esophageal ulceration in certain cardiac patients with esophageal compression due to enlarged left atrium.

All solid dosage forms of potassium chloride supplements are contraindicated in any patient in whom there is cause for arrest or delay in tablet passage through the gastrointestinal tract. In these instances, potassium supplementation should be with a liquid preparation.

WARNINGS: Hyperkalemia—In patients with impaired mechanisms for excreting potassium, the administration of potassium salts can produce hyperkalemia and cardiac arrest. This occurs most commonly in patients given potassium by the intravenous route but may also occur in patients given potassium orally. Potentially fatal hyperkalemia can develop rapidly and be asymptomatic. The use of potassium salts in patients with chronic renal disease, or any other condition which impairs potassium excretion, requires particularly careful monitoring of the serum potassium concentration and appropriate dosage adjustment.

Interaction with Potassium Sparing Diuretics—Hypokalemia should not be treated by the concomitant administration of potassium salts and a potassium-sparing diuretic (e.g., spironolactone or triamterene) since the simultaneous administration of these agents can produce severe hyperkalemia.

Gastrointestinal Lesions—Potassium chloride tablets have produced stenotic and/or ulcerative lesions of the small bowel and deaths. These lesions are caused by a high localized concentration of potassium ion in the region of a rapidly dissolving tablet which injures the bowel wall and thereby produces obstruction, hemorrhage or perforation.

K-DUR tablets contain micro-crystalloids which disperse upon disintegration of the tablet. These micro-crystalloids are formulated to provide a controlled release of potassium chloride. The dispersibility of the micro-crystalloids and the controlled release of ions from them are intended to minimize the possibility of a high local concentration near the gastrointestinal mucosa and the ability of the KCl to cause stenosis or ulceration. Other means of accomplishing this (e.g., incorporation of potassium chloride into a wax matrix) have reduced the frequency of such lesions to less than one per 100,000 patient years (compared to 40–50 per 100,000 patient years with enteric-coated potassium chloride) but have not eliminated them. The frequency of GI lesions with K-DUR tablets is, at present, unknown. K-DUR tablets should be discontinued immediately and the possibility of bowel obstruction or perforation considered if severe vomiting, abdominal pain, distention, or gastrointestinal bleeding occurs.

Metabolic Acidosis—Hypokalemia in patients with metabolic acidosis should be treated with an alkalinizing potassium salt such as potassium bicarbonate, potassium citrate, potassium acetate, or potassium gluconate.

PRECAUTIONS: The diagnosis of potassium depletion is ordinarily made by demonstrating hypokalemia in a patient with a clinical history suggesting some cause for potassium depletion. In interpreting the serum potassium level, the physician should bear in mind that acute alkalosis per se can produce hypokalemia in the absence of a deficit in total body potassium while acute acidosis per se can increase the serum potassium concentration into the normal range even in the presence of a reduced total body potassium. The treatment of potassium depletion, particularly in the presence of cardiac disease, renal disease, or acidosis requires careful attention to acid-base balance and appropriate monitoring of serum electrolytes, the electrocardiogram, and the clinical status of the patient.

Laboratory Tests: Regular serum potassium determinations are recommended. In addition, during the treatment of potassium depletion, careful attention should be paid to acid-base balance, other serum electrolyte levels, the electrocardiogram, and the clinical status of the patient, particularly in the presence of cardiac disease, renal disease, or acidosis.

Drug Interactions: Potassium-sparing diuretics, see **WARNINGS.**

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term carcinogenicity studies in animals have not been performed.

Pregnancy Category C: Animal reproduction studies have not been conducted with K-DUR. It is also not known whether K-DUR can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. K-DUR should be given to a pregnant woman only if clearly needed.

Nursing Mothers: The normal potassium ion content of human milk is about 13 mEq per liter. Since oral potassium becomes part of the body potassium pool, so long as body potassium is not excessive, the contribution of potassium chloride supplementation should have little or no effect on the level in human milk.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: One of the most severe adverse effects is hyperkalemia (see **CONTRAINDICATIONS, WARNINGS,** and **OVERDOSAGE**). There have also been reports of upper and lower gastrointestinal conditions including obstruction, bleeding, ulceration, and perforation (see **CONTRAINDICATIONS** and **WARNINGS**); other factors known to be associated with such conditions were present in many of these patients.

The most common adverse reactions to oral potassium salts are nausea, vomiting, abdominal discomfort, and diarrhea. These symptoms are due to irritation of the gastrointestinal tract and are best managed by taking the dose with meals or reducing the dose.

Skin rash has been reported rarely.

OVERDOSAGE: The administration of oral potassium salts to persons with normal excretory mechanisms for potassium rarely causes serious hyperkalemia. However, if excretory mechanisms are impaired or if potassium is administered too rapidly intravenously, potentially fatal hyperkalemia can result (see **CONTRAINDICATIONS** and **WARNINGS**). It is important to recognize that hyperkalemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration and characteristic electrocardiographic changes (peaking of T-waves, loss of P-waves, depression of S-T segment, and prolongation of the QT-interval). Late manifestations include muscle paralysis and cardiovascular collapse from cardiac arrest.

Treatment measures for hyperkalemia include the following:

1. Elimination of foods and medications containing potassium and of potassium-sparing diuretics.
2. Intravenous administration of 300 to 500 ml/hr of 10% dextrose solution containing 10–20 units of insulin per 1,000 ml.
3. Correction of acidosis, if present, with intravenous sodium bicarbonate.
4. Use of exchange resins, hemodialysis, or peritoneal dialysis.

In treating hyperkalemia, it should be recalled that in patients who have been stabilized on digitalis, too rapid a lowering of the serum potassium concentration can produce digitalis toxicity.

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ly accrued seniority and benefits, and the length of the leaves must be sufficient to fulfill their underlying purpose.

VI. GOVERNMENT INVOLVEMENT IN HEALTH RESEARCH

14. Do you support the use of animals in important biomedical research?

Bush: Over the decades, the use of animals in biomedical research has led to the eradication of many diseases, the alleviation of human suffering, and the general improvement of the health of mankind. Although biomedical research techniques today have become more technologically advanced and sophisticated, the use of animals continues to be necessary. We should not, however, allow animals to suffer unnecessarily. There is no reason why research animals should not be properly cared for.

Dukakis: Yes.

VII. UNCOMPENSATED CARE/UNINSURED PERSONS

15. What expansion, if any, of Medicaid would you support to deal with the issue of uncompensated care?

Bush: All but 17% of Americans have public or private health insurance to provide for their health care costs. They tend to be employees of small business--where the added cost of providing an employee health plan might ruin the business--costing the employee his job as well. We are looking at measures to resolve this problem. Another pressing issue is the catastrophic cost of long term care for chronic illness and disability. 1.5 million Americans are in nursing homes; many more are cared for at home. The problem will increase as America ages. I have proposed a program that includes the following points:

We should change the tax code to provide incentives for those who can afford to pay for long term care using group plan insurance.

We should allow conversion of IRAs, savings accounts, and life insurance so people can pay for long term health care.

For those seniors who cannot afford long term care insurance, we should change Medicaid requirements that force people to "spend down" their life savings before being eligible for assistance.

We also need to do more to promote the *option* of enrolling in innovative plans such as Health Maintenance Organizations (HMO) and Preferred Provider Organizations (PPO), and to induce competition among health care providers. Efficiencies are possible by making government--as well as private insurers--better consumers, and by creating the right kinds of tax and

program incentives for efficient, high-quality health care services.

Dukakis: It is high time that all of our citizens had basic health insurance in this country. That would be the most effective way to cover the health costs of those who are currently uninsured.

I have just proposed a plan for universal health care for all the citizens of my state. That plan would require all employers, with some exceptions, to provide basic health insurance for their workers and their dependents. Senator Kennedy has introduced similar legislation in Congress. Although I would propose certain modifications in the Kennedy legislation to address small business concerns, the Kennedy approach is one that I support. It would go a long way to providing basic health security for most Americans. And today, 40 million American citizens have no health insurance of any kind.

16. Would you support legislation to require all employers to provide some minimum level of health insurance benefits to their full and part time employees?

Bush: See comment to question 15.

Dukakis: See comment to question 15.

VIII. HEALTH POLICY

17. Do you agree or disagree that the problems associated with rising medical care costs and difficulties in gaining access to care require resolution through federal planning and federal dollars?

Bush: A Bush Administration will address these problems by controlling costs and providing more comprehensive coverage under Medicare.

Several principles must guide this effort. First, the less that government is involved in the day-to-day administration of health care, the more efficiently it will run--which, of course, means that we should shun the various Democrat health care proposals which would involve government bureaucrats in people's personal health care decisions. Second, more efficient administration of health care must be encouraged--and in particular, the government health programs such as Medicaid and Medicare should not fund waste and inefficiency. And third, we must limit the incentives and ability for patients to file frivolous malpractice suits which drive health care costs up for all Americans.

Dukakis: Agree. With well crafted policy emphasizing public/private partnerships, I believe that the private sector can do most of the job in providing decent health care for our citizens.

However, serious gaps persist. As I mentioned earlier, I favor Senator Kennedy's bill now in Congress that would make available health care coverage to millions of working Americans who lack coverage of any kind.

Moreover, as President, I would require Medicare to pay for home health care services already covered by law.

Thus, when it comes to the most efficient delivery of health care, I do not subscribe to sweeping theories. Our approach should be pragmatic and compassionate. Although the private sector can do most of the job, we should be prepared to fill in the gaps with private/public partnerships, state spending, and with federal dollars when necessary.

IX. PAC LEGISLATION

18. Do you favor public financing of congressional elections?

Bush: I believe strongly in the right of individuals and groups to use their resources to promote their ideas and goals. It is an inherent part of one of our most basic rights, the freedom of speech. At the same time, I recognize that there have been abuses in the electoral system which have required reforms.

As part of those reforms, I have supported public campaign financing of Presidential elections. However, I

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do not believe that the current proposals in Congress for the public financing of 435 Congressional elections and 33-34 Senatorial elections every two years will result in wise policy.

The most important of all campaign reforms has already been achieved--financial disclosure of receipts and expenditures. I have long supported full disclosure laws and believe it must be kept strong to prevent ethical misconduct. In keeping with the spirit of campaign laws, I have disclosed my tax returns.

Dukakis: Yes.

19. If YES, please explain what type of program you would propose (such as total financing, limitation, matching funds, etc).

Bush: See comment to question 18.

Dukakis: PACs are not charitable organizations which support political campaigns for civic purposes. They have particular interests on which they expect support in exchange for their contributions.

To curtail the influence of wealth in politics, there should be absolute limits on campaign expenditures in congressional elections just as there now are in presidential elections. PAC contributions should either be forbidden or drastically curtailed. The amount of money that can be contributed by candidates and their immediate family should be limited also as in presidential campaigns. Consistent with constitutional law and as also is the case in presidential elections, partial public financing of congressional elections up to the amount of expenditure limits should be provided for candidates who have agreed to accept the expenditure limits and have demonstrated broad support by receiving small contributions from a significant percentage of their electorate.

I support the basic provisions for the Boren-Byrd Senatorial Election Campaign Act (S.2).

The above information was collected in response to a questionnaire mailed to presidential candidates by the American Medical Association regarding their opinions on major health issues. Replies were previously printed in the February 26, 1988 issue of American Medical News.

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Introduction

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Through the years, this tradition of dependability has earned CNA a reputation for stability and experience in continuing to meet the long-term commitment of the physicians professional liability insurance market.

Program Objectives
CNA believes that in choosing a professional liability insurance company, it's important for the company to meet the following objectives:

- Provide broad coverage to meet the needs of practicing physicians.
- Provide insured physicians with financial protection.
- Stabilize rates for participants in the program.
- Promptly and fairly resolve legitimate claims.

Expertise
CNA has been providing professional liability insurance to physicians for over 20 years and, in that time, has become an industry leader. Their experience in writing professional liability programs has resulted in a special understanding of the needs of this market and some of the finest professional liability programs available today.

One important aspect of CNA's programs is expert claims handling. CNA recognizes that claims handling plays a vital role in any professional liability program, and is committed to providing prompt, efficient claims service to all insureds.

"CNA is dedicated to promptly and fairly resolving legitimate claims, while providing an aggressive defense against non-meritorious claims."

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Financial Strength
CNA is one of America's leading financial institutions. With over $19.6 billion in assets and $1.9 billion in surp they have the size and resources to adequately financ professional liability programs. You can count on them stay in the market and be there when you need them.

CNA's financial standing and stability have not gone unnoticed. Continental Casualty Company, CNA's primary professional liability underwriter, has an A+ rating — the highest rating available from A.M. Best, the definitive source for information on insurance organizations. This rating represents a very significan barometer for CNA's financial and operating strength

Major Features of the CNA Physicians Protection Program

Protection
The Physicians Protection Program provides coverag for damages arising from the performance of or failur to perform professional services in your capacity as a physician or surgeon, or the performance of professio medical services by any person or organization, inclu nurses, nurse anesthetists, physician assistants, and others for whose acts or omissions you are legally liab

Liability limits available:

Per Claim Limits	Annual Aggregate Limits
1. $1,000,000	$1,000,000
2. $1,000,000	$3,000,000
3. $2,000,000	$4,000,000
4. $3,000,000	$5,000,000
5. $4,000,000	$4,000,000
6. $5,000,000	$5,000,000

Extended Reporting Option (TAIL)
In the event of death, disability, or retirement by the physician, no charge shall be made for this coverage provided that during the policy period:

A. death or total and permanent disability occurs; or

B. retirement takes place after the physician has reach the age of 60; and

C. the physician has been continuously insured by us the immediately preceding 5 years.

Antitrust Coverage
Antitrust coverage is provided for activity as a membe of any committee, panel or board which provides pee review, provided that your activity is within the scope of the committee's, panel's or board's established guidelines. All other antitrust exposures are excluded.

Contractual Liability
Contractual liability protection includes liability assumed by contract with an HMO, PPO, IPA, or other similar organizations but only for such liability as is attributable to the CNA-insured physicians' negligence.

Employees: (Ancillary Personnel)
The following ancillary personnel may be added to the Corporation policy as additional insureds at no additional charge, provided that limits of liability are on a shared basis.

Audiologist	Optometrist
Medical Aide	Pharmacist
M.D.	O.R. Technician
R.N.	Physiotherapist
Psychologist	Dental Hygienist
Full Time Medical Student	Scrub Nurse
EKG Technician	X-Ray Technician
Medical Laboratory Technician	with/without Therapy
Research PhD	

The following ancillary personnel may be added to the Corporation policy (individual physician's policy if no Corporation policy) as additional named insureds for an additional premium. Limits of liability must equal those of the Corporation (individual) and shall apply separately to each individual.

Midwife	Paramedic
Nurse Anesthetist	Physician Assistant
Nurse Practitioner	Scrub Nurse
O.R. Technician	Surgeon Assistant

Defendant Reimbursement
Defendant Reimbursement is available (up to $300 per day, $7,500 limit) for time away from your practice for court appearances for a professional liability suit.

Partnerships and Corporations
It shall be possible to provide coverage for our insured's medical corporation or partnership for liability arising from the practice of medicine by the member physician(s), provided that the member physician(s) is insured by CNA:

A When an individual physician is incorporated and sole shareholder, the corporation shall be covered as an additional insured, on the individual physician's policy, at no additional premium. Limits of liability shall be shared with the individual physician.

B Coverage for a multi-member group shall be provided on a separate limits basis by issuing a separate policy naming the corporation/partnership. The limits of liability must equal those of the individual member physicians. An additional premium must be paid for this coverage.

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Book Reviews

William L. Jaffee, M.D., Book Review Editor

BREAST CANCER: DIAGNOSIS AND TREATMENT, by **Irving M. Ariel** and **Joseph B. Cleary.** 1987; New York: McGraw-Hill Books. 577 pp. Price unavailable.

Perhaps many physicians found, as I did, that learning about breast cancer was a difficult task during student years. The information in most basic textbooks was often sparse and outdated, or in some cases too complex and confusing. Furthermore, there has been an avalanche of studies from specialists advocating pet therapies or a multidisciplinary approach. The physician in today's medical world must decide what is best for treating their breast cancer patients, and these decisions will be subject to the patient's informed consent.

This book offers the physician an excellent guide to the management of breast cancer. The authors have constructed a well organized book with a logical approach to their subject. First, a historical review is given of past efforts used to treat breast cancer. The next chapters deal with patient risk factors. There is an excellent section on the role of heredity in the etiology of breast cancer, the identification of high risk patients, and the establishment of special surveillance for their monitoring.

The authors then proceed to the basic considerations of classification, pathology, receptors, and immunology. Methods of detecting and diagnosing breast cancers are discussed. This includes the results of mammographic screening, other imaging techniques, and the various methods used for obtaining a biopsy.

The central portion of the book is devoted to various options open to the physician trying to cure the patient with breast cancer. Each treatment with the specific indications, complications, and results are presented for different types and stages of breast cancer. The treatment of advanced cancer follows. The role of surgery, radiation, and chemotherapy is reported in an accurate and objective manner.

Finally, after a section on reconstruction the authors deal with special clinical situations and the support of the breast cancer patient. They end with a chapter on "The Law of Informed Consent and Mastectomy," in which current legal issues are raised.

This book is not a surgical atlas, nor is it a cookbook with precise instructions on chemotherapy regimens or radiation treatment. However, the authors have been able to sort through the mountain of studies and research to simplify the results and present their information in a unified manner. Each reader can decide what is the best method for the management of their breast cancer patients. The book is easy to read and understand, and I only regret it was not available during my residency program.

J. Wesley Clayton, III, M.D.

POCKET ATLAS OF MRI BODY ANATOMY, by **Thomas H. Berquist, M.D., Richard L. Ehman, M.D.,** and **Gerald R. May, M.D.** 1987; New York: Raven Press. 100 pages. Price $12.50.

Slices through hands, legs, joints, the heart, the neck—the black and white images revealed by MRI are clear enough for non-anatomists to understand when pointed out to them, even if they cannot themselves identify the organs without the aid of photographs such as these.

From Plate 1 on Shoulder/Axial Image through Plate 95 on Ankle/Sagittal Image (no head!) this Pocket Atlas of MRI is fascinating. The preface misspeaks; cerebral anatomy is not in this volume. Perhaps there is or will be a companion which includes the head. I hope so.

Bernadine Z. Paulshock, M.D.

NELSON'S TEXTBOOK OF PEDIATRICS, edited by **Richard C. Behrman, M.D., Victor C. Vaughan, III, M.D.**, and **Waldo E. Nelson, M.D.** 1987; Philadelphia: W.B. Saunders. 1640 pp. Price $85.00.

This is the thirteenth edition of this classic text. The first edition was published in 1933. The three editors are Professors of Pediatrics at Case Western Reserve, Temple, and Medical College of Pennsylvania, respectively. There are 124 other contributors, including Michael E. Norman, M.D., who is listed as Professor and Associate Chairman, Department of Pediatrics, Jefferson Medical College, and director, Department of Pediatrics, Medical Center of Delaware. The great majority of the contributors are practicing pediatricians from medical schools across the country.

This is a definitive text for reference, not a book aimed for reading leisurely by the fireplace. Yet sections of it are highly readable. The editors make the observation that pediatrics has come a long way. In the late nineteenth century, of every 1,000 infants born alive, 200 died before their first birthday of dysentery, pneumonia, and the childhood diseases. They credit the improvement to the combined effects of sanitation, immunization, better nutrition, and antibiotics. And yet today non-white children in the United States lag far behind. For the socioeconomically disadvantaged, public programs are poorly coordinated and inadequately funded, the editors say.

Although this text is organized in accordance with the usual scheme of organ system disorders, it gives emphasis throughout to cultural and psychosocial considerations in the child's growth and development.

The editors say that the amount of information relevant to child health care doubles every eight to ten years. Their text is an effort to give the practitioner a place to get up-to-date answers to clinical questions.

David Platt, M.D.

CARDIOVASCULAR ANESTHESIA, by **Carol L. Lake.** 1986; New York; Springer-Verlag. 467 pp. Price $ 54.50.

In her book, Carol L. Lake reviews the various types of cardiac disease with which patients may present to the operating room and how to manage their anesthetic courses so as to avoid further compromise of hemodynamic function. Since many of our geriatric population probably has coronary artery disease, the subject matter is relevant to the anesthetic management of most surgical procedures on our elderly patients, and it clearly is relevant to helping the patient with overt symptoms of cardiac disease through the perioperative period.

There are 22 chapters in the book, of which seven are specific for open heart procedures. The initial three chapters neatly summarize fundamentals of cardiac physiology and hemodynamic assessment and monitoring. Several other chapters are devoted to particular cardiac problems including coronary artery disease (Chapter 5), valvular heart disease (Chapter 6), congenital heart disease (Chapter 7), and pericardial disease (Chapter 22). Overall, the author covers a similar spectrum of material seen in other books on the subject.

One chapter, devoted entirely to complications of cardiac surgery, is somewhat unique in this genre and is an excellent summarization of common complications which should be anticipated by the entire cardiac team.

Generally, the chapters are well written, broadly cover the individual subjects, yet are fairly concise. Each chapter can be comfortably read in one or two nights. For the neophyte in these matters, the chapters are not exhausting in detail, making them easy to read. On the other hand, the anesthesiologist will find the lack of depth unsatisfying. Even the author admits in Chapter 10, "Pharmacology of Cardiac Drugs," that an exhaustive review of the subject is beyond the scope of the chapter, and refers the reader to Kaplan's *Cardiovascular Pharmacology.* However, the book is extreme-

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ly well referenced and may be an asset to the specialist simply as a resource book. For instance, Chapter 3 alone contains 250 references. The author manages to pick the essential point out of the vast majority of references cited. However, many of these conclusions are not critically examined, and may mislead the uninitiated. For instance, although the often-cited hemodynamic monitoring study by Rao, et al, in *Anesthesiology* is discussed, the important editorial which accompanied the article and challenged its conclusions is never mentioned.

This book will probably be most appealing to residents in anesthesia and to non-cardiac anesthesia staff wanting to keep abreast of developments in the field. Overall, it is an excellent first book on this complex subject.

Eugene I. Tolpin, M.D.

STORIES OF SICKNESS, by **Howard Brody, M.D.** 1987; New Haven, Connecticut: Yale University Press. 210 pp. Price $27.00.

The author of this book actively practices family medicine and teaches in both the Family Medicine Department and the Medical Humanities Program of Michigan State University.

His plea is that each patient's illness fits into the story of his life, and if we will only let him and encourage him to do it in his own way, the patient will tell it to us. He illustrated this by actual case histories, and also by examples from literature, including Thomas Mann's *The Magic Mountain* and Aleksandr Solzhenitzyn's *The Cancer Ward*. Brody urges that instead of having courses in medical ethics, medical schools should teach ethics by having students read and discuss stories of sickness in the great literature of the world.

The closing sentence in this book is, "We hope that as physicians pay more attention to the stories of the patients, their ethical quest to enhance personal autonomy and self respect in the wake of sickness will be aided by an increased awareness of the richness of the human response to illness and anguish."

David Platt, M.D.

DISEASE AND DISCOVERY: A HISTORY OF THE JOHNS HOPKINS SCHOOL OF HYGIENE AND PUBLIC HEALTH, by **Elizabeth Fee**. 1987; Baltimore: Johns Hopkins University Press. 286 pp. Price $30.00.

This is a detailed, exhaustive discussion of the foundation and operation of the Johns Hopkins School of

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Hygiene and Public Health. To understand public health policy, there is first an explanation of the history and philosophy of public health, not only in the United States but in the Western World. The sociological and political influences of the public health movement are examined. Should one treat and contain infection and the infectious persons, or should one try to change society to prevent the disease? Such controversies were integral to the organization and administration of the first School of Public Health. The characteristics and strength of the first professors are recounted, as well as their investigations and discoveries.

This book is mired in exquisite detail. It is hard to imagine for whom it is intended. Certainly, the student of the history of public health may enjoy it, if they are interested in both the history of the philosophies of public health as well as the intricacies of starting a new school. Anyone with a particular interest in any of the doctors or teachers involved will find endless particulars. As a resource it is invaluable, but it is unlikely it will become general reading.

Jo Ann Rosenfeld, M.D.

THE CHANGING HUMORS OF PORTSMOUTH: THE MEDICAL BIOGRAPHY OF AN AMERICAN TOWN, 1623 - 1983, by **J. Worth Estes, M.D.** and **David M. Goodman, Ph.D.** 1987. F.A. Countway Library of Medicine. Price unavailable.

This volume was originally conceived as merely a history of the 100 years of the Portsmouth Hospital, but the committee selected to oversee the project altered the objective to encompass the entire 360 years of medicine in Portsmouth, New Hampshire, with the hospital placed in that broader context.

The story of medicine in Portsmouth gives a good picture of American medicine in many of its aspects. Medical practice from 1631 to about 1840 was characterized by a great reliance on a few remedies like digitalis, opium, and mercurials, with bleeding and purging two of the most commonly applied therapies. Most patients got well despite their treatment and despite the lack of knowledge as to how some of the medications worked.

An interesting archeological note related in the book sheds some insight into the therapy of those early days. The excavation of the Hart-Shortridge House,

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in which from four to six people lived in the early 19th century, revealed that they had used from 17 to 19 chamber pots. Presumably patients taking daily doses of cathartics such as calomel would each need several of these receptacles at hand.

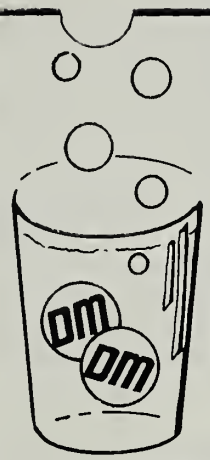
When Portsmouth first acquired a hospital in 1884, there were only about 180 hospitals in the entire United States. What occurred in Portsmouth is similar to what was beginning in Wilmington at about the same time, and in both instances the initiation of the hospital was a result of concerned women. Between the 1880s and 1910, the number of hospitals in the United States increased to over 4,000.

In the first 100 years of the Portsmouth hospital's life, the founding women directors managed it for 35 years, and then were gradually ousted from control by the male trustees who controlled the purse strings, and who relegated the women to the level of a volunteer affiliate called the Hospital Guild. The trustees, however, did not do such a good job, as subsequent events were to prove. Also it should be noted that after 40 years the women got back into the decision making level, when in 1960 a woman was elected president of the trustees.

My impression is that the Portsmouth community and its doctors were always behind the times, partly because money was tight. Its first x-ray machine was acquired in 1916, and its first electrocardiograph was obtained for the hospital only in 1956. The medical staff was not unaware of what was going on in terms of medical technology since most had been trained in major medical centers, but there was a general lack of energy and rapport between the trustees, the doctors, and the community at large. Finally a crisis developed due to a growing deficit, a declining census, and more pressures from the government and the Joint Commission on the Accreditation of Hospitals to make changes for which there were insufficient funds.

A study was done by an outside consulting firm which offered several unpleasant alternatives for the hospital trustees to consider, none of which met with much enthusiasm. An alternative was pursued which involved the sale of the hospital to the Hospital Corporation of America, and so the hospital was rescued from bankruptcy, but became proprietary.

This is a sad story when taken overall. There had been moments in the 360 year history when some of the doctors were examples of the very best in American medicine. But on balance the small town of Portsmouth became a medical backwater and failed to keep the faith with which the women started their hospital and which blossomed from time to time, only to be lost in selfish behavior, shortsighted actions by doc-



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tors, businessmen, and elements in the community who failed to recognize that this resource needed cultivating and support or else it would shrivel and, if not die, metamorphose into something alien. No one knows how this will play out in the next 100 years, but from reading this book it seems to me that Portsmouth is destined to live in Boston's shadow and not attain the quality of medical practice it sometimes achieved in the past.

The book makes interesting reading as a vignette of medicine in the United States seen after more than 300 years. It is well researched and written by two experts. Did you know that the word "vaccination" comes from the Latin word for "cow"--*vacca*, the feminine of *vaccinus*?

Norman L. Cannon, M.D.

Dr. Cannon is the author of *The History of a Hospital Merger: The History of the Wilmington Medical Center, 1965-1985.*

CONTROL OF COMMUNICABLE DISEASES IN MAN, FOURTEENTH EDITION, edited by **Abram S. Benenson.** 1985; Washington, D.C.: American Public Health Association. 485 pp. Price unavailable.

The American Public Health Association published the first edition of this book in 1917. Now in its fourteenth edition, the next is expected in five years.

The diseases are presented in alphabetical order. Each disease is discussed in a standardized fashion. First, a brief clinical presentation of the disease is given, followed by the infectious agent, occurrence, reservoir, mode of transmission, incubation period, period of communicability, susceptibility, and resistance. Next, the method of control is given under five subheadings: preventive measures; control of patient contact and the immediate environment; epidemic measures; disaster implications; and international measures.

Of particular interest are the new topics included such as AIDS, malignant neoplasia, cryptosporidiosis, Kawasaki syndrome, and hymenolepiasis. The book is directed toward a broad group of health professionals: physicians, dentists, veterinarians, sanitation engineers, public health workers, social workers, health administrators, etc.

The handbook is highly organized in its presentation. At the end of the text is a chapter on definition of terms most commonly used in communicable disease. It serves not only as a refresher for the health care professional, but for anyone who is not familiar with the terminology used in communicable disease. I would recommend this handbook to anyone who sees or treats communicable diseases.

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President's Page

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This is the time of year when a variety of appeals go forth to the community. The 1988 United Way campaign, now nearing completion, has once again generated solid support for its member agencies throughout Delaware. Very likely, you have been receiving solicitation appeals from college and medical school alumni offices. Other appeals emanate from myriad not-for-profit organizations which enrich the lives of Delaware's citizens.

This year, however, there is a special appeal underway to benefit a small, but very important, group of our fellow citizens...the families of seriously ill children being treated at our excellent pediatric inpatient facilities. I think that this appeal merits your consideration and solid support.

The community need is clear. Delaware has no place for the families of these children to stay while their child is undergoing treatment for serious illness or injury. We are becoming an international center for pediatric health care. Wilmington area hospitals alone treated almost 1400 children from outside New Castle County last year, some from as far away as Eastern Europe and Asia. Extended hospitalizations are costly for families of these children, both in terms of dollars and personal relationships.

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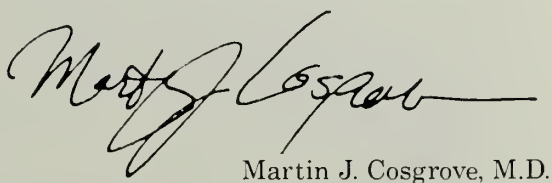
The groundwork has been completed for the project. We Care In Delaware, a community organization comprised of parents, community volunteers, physicians, and hospital executives, has conducted a feasibility study of the project. The study concluded that there is broad public support for building a Ronald McDonald House convenient to Christiana and St. Francis Hospitals and to the A.I. DuPont Institute. In addition, the Association of Delaware Hospitals and its member institutions, as well as the Delaware Chapters of the American Academy of Pediatrics have endorsed the project.

Since its formation in 1986, We Care In Delaware has received more than $500,000 from advance gifts, benefits, commitments from Ronald McDonald Children's Charities, and the 1988 LPGA Gold Tournament, as well as the offer of a building site for the 16-bedroom House from the State of Delaware.

Now, contributions and pledges are being sought to meet the remaining $1.5 million in construction costs. The physician community throughout Delaware can demonstrate its support of this worthwhile project by contributing generously when asked by the volunteer campaign solicitors. Please support the Ronald McDonald House for Delaware.



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VOLUME 60 SEPTEMBER 1988 NUMBER 9

SPECIAL ISSUE ON MEDICAL ETHICS
Maurice Liebesman, M.D., Guest Editor

411 PRESIDENT'S PAGE
R_X-Physician Political Involvement

475 EDITORIALS
Medical Ethics: A Rediscovered Discipline
Maurice Liebesman, M.D.
Informed Consent: An Ethics Question?
Robert W. Frelick, M.D.
AIDS Hysteria in Delaware
Diana Dickson-Witmer, M.D.
Care of the Brain Dead and Other Troubling Patients
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Quandaries in Reproductive Technology
Jeffry I. Komins, M.D.
Medical Need and the Private Practice Physician
David Platt, M.D.
Saving Our Ozone Layer: The DuPont Company's Decision
Bernadine Z. Paulshock, M.D.

479 AIDS AS AN OCCUPATIONAL DISEASE: WHOSE RIGHT TO KNOW?
Lawrence Gostin, Esq.

487 ABORTION IN ADOLESCENCE: A CLINICIAN'S REFLECTIONS
Tomas J. Silber, M.D., M.A.S.S.

491 MEDICAL ETHICS IN MEDICAL PRACTICE
Robert L. Perkel, M.D.

497 ETHICAL CONSIDERATIONS IN SOLID ORGAN TRANSPLANTS
John Noseworthy, M.D.

505 RELIGIOUS PERSPECTIVES
A Catholic Perspective on Religion and Organ Transplantation
Thomas R. Ulshafer, S.S., Ph.D.
Choose Life: Jewish Tradition and Organ Transplantation
Kenneth S. Cohen
John 15:13: A Protestant's View of Organ Donation
Marlene Walters, Ph.D.

519 BIOETHICAL HUMOR
Dr. Aap

535 DEATHS
Philip Reed Walker, M.D.
George J. Boines, M.D.

539 IN BRIEF

COVER
Provided by Maurice Liebesman, M.D.

NOTE: Because of the special nature of the August issue of *Delaware Medical Journal,* it has been deleted from the consecutive numbering system reflected throughout Volume 60. Bound volumes will reflect the proper numerical sequence, and a special notation for the August issue will be made in the volume's index.

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President's Page

R_X--PHYSICIAN POLITICAL INVOLVEMENT

Across the length and breadth of this state and this nation, concerned and responsible citizens have begun participation at every level in that uniquely American political process--an election campaign.

However, in an election campaign in which the major candidates espouse very definite and divergent health care views and in which health care issues may well play a major domestic role, only 46% of physicians nationwide are even registered to vote.

Considerable individual failure of physicians as voting citizens is mirrored in the lack of support for the AMA and the Political Action Committee of the AMA, AMPAC. Only 46% of the United States' physicians belong to the AMA. Of these AMA members, only 11% are members of AMPAC.

We have witnessed the socialization and the eventual deterioration of health care systems in neighboring and kindred nations. Our fees are arbitrarily frozen by the federal government. Individual states impose capricious and discriminatory conditions for medical licensure. We currently struggle and cope with the constraints of the DRG system and the resultant hardships inflicted upon our patients. We face in the impending RVS system the greatest change in the practice and economics of medicine in the past 30 years. Malpractice continues to adversely affect the quality and cost of health care.

The individual and collective response of physicians to these and other challenges has largely been noninvolvement and withdrawal from the political process, the very process that may effect solutions.

As physicians, we have a dual responsibility. We are citizens and have an individual obligation to vote. We also have a responsibility as physicians to be the advocates of quality health care for our patients. Our patients comprise all the voters of the state of Delaware. We must speak out on health care issues individually to our patients and through organized medicine and our political action committees at the county, state, and national levels.

I urge all members of the Medical Society of Delaware to become more involved in the political process in this election year. Acquaint yourselves with all the political issues, particularly those regarding medicine. Become health care information resources to your local legislators. It is important that you personally and financially support both the candidates of your choice and the splendid efforts of AMPAC and DELPAC.

Martin J Cosgrove, M.D.

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Editorials

MEDICAL ETHICS: A REDISCOVERED DISCIPLINE

When Dr. Bernadine Paulshock invited me to once again be guest editor for a second special issue on Medical Ethics for *Delaware Medical Journal*, I was flattered, but also concerned because of that superstitious fear that second parts are never as good as the original. And also because I sensed that medical ethics, being a rediscovered discipline in the realms of medicine, could occasionally cause a confrontation between the *new* doctors who are being taught a more contemporary approach to medicine, with their *seniors*, who are already set in their own "old" ways.

If there is a reciprocal relationship between *paternalism* and *autonomy*, I would like to use it when analyzing the way we practice medicine at the present time. Nowadays, patients expect to be given the right to ask questions and to be part of the decision making process with regards to their treatment. But I am afraid that the majority of the physicians today providing care acquired a paternalistic attitude as a result of their medical education prior to the '80s. Including myself. I'm in the process of making the necessary changes that I hope will place me in the mainstream of the practice of medicine in the future.

When I accepted the charge of editing this issue of *Delaware Medical Journal*, there seemed to be nothing but AIDS splashed all over the media. In the lay press and in the medical literature, in the corridors of hospitals and in the aisles of supermarkets, we were hypnotized by a disease that caught us by surprise and unprepared. Discoveries and retractions were published almost daily. Even the CDC has to periodically review its guidelines. The questions most often asked are related to the risk of contamination in a hospital setting: How to protect the health care worker from an infected patient? How to protect the patient from an infected health care worker? Will screening for HIV reduce the risk of transmission? To shed light on these quandaries, I turned to an expert in the medical-legal field: Lawrence Gostin, Esq., Executive Director of the American Society for Law and Medicine, who makes an excellent presentation by taking us through those questions to his final answers, and he does it in a clear and scholarly manner. I consider his paper a gem in this issue.

Dr. Tomas Silber, a friend of mine from Washington D.C., is an unusual combination of physician-philosopher who enjoys both disciplines. I had the opportunity to meet and discuss with him the sudden interest of medicine in bioethics, and we both agreed that it may be the result of the explosive technical progress in con-

(Continued on page 523)

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VOLUME 60
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SEPTEMBER 1988

AIDS AS AN OCCUPATIONAL DISEASE: WHOSE RIGHT TO KNOW?

Lawrence Gostin, Esquire

Introduction

Screening for the human immunodeficiency virus (HIV) in health care facilities has become a pressing issue, despite the evidence that occupational risks are remote.[1-6] Health care workers believe they have a "right to know" the serological status of their patients. Dr. Everett Koop has called for HIV screening of all preoperative patients.[7] Some hospitals already screen their patients without specific informed consent.[8-11]

Patients also want to know if their physician is infected with HIV. In a Gallup Poll sample taken in 1987, 86% of the respondents said patients should be told if their physician has AIDS.[12,13] Most patients would choose not to receive treatment from an infected physician.

The prospect of a "right to know" the health status of both doctor and patient, with calls for screening on both sides undermines trust within the health care system.

In this article I examine the competing claims of the physician and the patient for compulsory screening. I argue that the case for compulsory screening for either group has not been established because: (1) the risk of HIV transmission in health care settings is remote; (2) screening would not decrease risk; and (3) the human and economic costs of screening are wholly disappropriate to the marginal public health benefit sought to be achieved.

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This article is an outgrowth of previously published articles by members of the Harvard School of Public Health.

The Risk of HIV Transmission in Health Care Settings is Remote

The risks of transmission of HIV in the health care setting have been thoroughly studied and shown to be low.[1-6] As of July 10, 1987, a total of 1,875 (5.8%) of 32,395 adults with AIDS were employed in a health care or clinical laboratory setting. This compares with a total of 4.8 million health care workers, representing 5.6% of the national workforce. Of the health care workers with AIDS, only 5% are not reported to exhibit high risk behavior such as homosexual contact or shared use of needles. Moreover, the percentage of health care workers with undetermined risk has not increased since 1982.[7]

AIDS patients initially reported as not belonging to a recognized risk group have been further investigated. The results of these investigations show that it is exceedingly rare for health care workers to seroconvert due to occupational exposure. Only a small number of cases of occupational exposure have been documented: three from needlestick accidents,[8-11] two from providing nursing care,[12,13] and three from non-needlestick exposures to contaminated blood.[14] These studies of health care workers are consistent with other research which demonstrates that HIV is difficult to transmit even in highly intimate household settings.[15,16]

The eight reported cases of occupational exposure to HIV appear insignificant given the frequency of contacts between health care workers and HIV infected patients. Several prospective studies show there is risk in the range of .03-.09%

that a health care worker will contract HIV following a documented case of percutaneous or mucous membrane exposure to HIV infected blood.[7,17] This is relatively low compared with the risk of 12-17% seroconversion after accidental percutaneous injection from patients with hepatitis B, even after passive immunization of recipients by immune serum globulin.[18]

In sum, considerable evidence now demonstrates that health care settings do not pose an unusually high risk of transmission of HIV that would justify mandatory screening. The reasons for this conclusion are that hospital patients are predominantly the elderly and the very young, two categories least likely to harbor HIV; routine medical and nursing procedures do not create a significant risk of exposure to HIV; and even percutaneous or mucous membrane exposure usually does not lead to seroconversion.

Screening Would Not Decrease the Risk of HIV Transmission

Suppose the risk of AIDS transmission in health care settings were considerably greater than research has thus far indicated. Mandatory screening would still be justifiable only if it significantly reduced the rate of transmission. That is, information that a person is HIV positive would lead to some action to reduce the risk of transmission which would not be taken if the information were unavailable. Information that a patient is seropositive is of very limited use to the physician. Physicians have a professional,[19] as well as a legal,[20] responsibility to treat infected persons. It is not usually possible to use different methods for treating HIV positive patients to reduce the risk of contracting the infection; and in some cases different methods could result in prolongation of operative time, potentially having an adverse effect on the patient.[7]

The Centers for Disease Control (CDC)[7] recommends, and the Occupational Health and Safety Administration (OSHA)[21] requires, the universal application of barrier protection in all cases of potential exposure to blood. The U.S. Public Health Service emphasizes the need to consider all patients as potentially infected with HIV and other blood-borne pathogens and to adhere rigorously to infection control precautions for minimizing the risk of exposure to blood and body fluids for all patients.[7] These precautions include routine use of appropriate barrier protection to prevent skin and mucous membrane exposure when contact with bodily fluids is anticipated, washing immediately and thoroughly if skin is contaminated with body fluids, taking precautions to prevent needlestick injuries, minimizing the need for mouth-to-mouth resuscitation, and refraining from direct patient care if the health care worker has a lesion or weeping dermatitis. If Public Health Service guidelines are carefully followed, they will minimize the risk of transmission of HIV in health care settings.

Health care workers are understandably concerned about occupational risks, particularly following reports of seroconversion from skin exposure to contaminated blood. But the only way to significantly reduce the occupational risk is to rigorously comply with infection control guidelines. Universal screening of hospital patients will not achieve the goal of consistent compliance with infection control guidelines. Indeed, it is conceivable that screening would provide a false sense of security and result in carelessness when treating negatively tested patients.

Screening merely indicates whether a patient has antibody to HIV at a particular point in time. Although the ELISA is highly sensitive, it is well recognized that there is a window of time, ranging from weeks to months, where a person may be infected but not develop the antibody. A recent study indicates that this window period may be considerably longer in some cases, lasting for up to a year or more. Screening programs therefore would detect most--but not all--cases of infected patients. If health care workers were falsely reassured that a patient was seronegative, they might not follow necessary infection control guidelines when working with that patient.

Screening of all hospital patients, then, would not be an efficacious public health program. There is at present little documented risk of HIV transmission in health care settings, and universal precautions should be taken regardless of the results of any test. This conclusion is shared by each of the public health authorities that has considered the subject: The World Health Organization, the U.S. Public Health Service, and the American Medical Association (AMA).[22]

The social, personal, and financial costs of screening would be wholly disproportionate to the marginal public health benefit.[23] The disadvantages of screening in health care settings are similar to those in other low risk populations.

Even excellent scientific tests such as ELISA do not perform well in low prevalence populations. Our group at Harvard estimates that the ELISA, even with confirmatory Western Blot testing, would generate a false positive rate of 25% in a low risk population such as marriage applications.[24] A positive test result in a person who is not infected could have devastating personal consequences. The potential for false negative results would also necessitate periodic re-testing at considerable expense to the health care facility.

Systematic collection of highly sensitive health care data would place considerable burdens on the hospital. Hospitals would be required to keep the information confidential and could be liable for intentional or negligent disclosure.[25] The courts and parties to litigation might seek access to the data. Hospitals would also have to decide whether to disclose the information to patients or third parties under a duty to warn theory.

Finally, a systematic program of HIV screening without informed consent might well be unconstitutional. Patients and health care workers have Fourth Amendment rights to be free from unreasonable infringements on their right to privacy. One federal court already held unconstitutional a screening program of staff at a mental retardation facility because the risk of transmission of HIV "is extremely low and approaches zero."[26]

The HIV Infected Physician

If surgeons assert the right to screen patients, it leaves the door open for patients to assert an equivalent right. The rights and responsibilities of physicians and patients are, to a large extent, symmetrical. It is reasonable to assume that the risk of transmission of HIV, although very small, runs in both directions. It is true that the health care workers who cut or puncture themselves do not necessarily expose the patient to their blood, and even if they do the volume is extremely small. A small inoculum of contaminated blood is unlikely to transmit the virus.[27] Nonetheless, an infected physician, such as an orthopedic surgeon who performs seriously invasive procedures can expect to carry out numerous operations during a normal professional career. That surgeon is in significant contact with the patient's blood and organs, and is prone to tear surgical gloves on sharp instruments or bone fragments. The risk that one of the surgeon's patients will seroconvert is more than negligible. The cumulative risk to patients from an HIV infected surgeon appears at least as great as the risk to the surgeon.

An analysis of proposals for mandatory screening should be applicable to surgeons as well as patients. At the very least, when the government, professional associations, or hospitals call for mandatory screening of patients, they should justify why the same reasoning does not apply to health care workers performing seriously invasive procedures.

The evolving standard of medical care is for HIV infected physicians to refrain from performing seriously invasive procedures if there is a risk. The AMA concluded that a "physician who knows that he or she has an infectious disease should not engage in any activity that creates a risk of transmission of the disease to others...even minimally."[19] The General Medical Council of Great Britain, a statutory body concerned with physician discipline, ruled that it is "unethical for doctors who know or believe themselves to be infected with HIV to put patients at risk."[28]

While the Public Health Service[7] and medical associations have indicated that HIV infected physicians may pose unacceptable risks for patients when they perform certain medical procedures, they have not specified which procedures. In each case, HIV infected physicians are told to seek advice and counseling from their personal physician, employing hospital, and colleagues to determine any restrictions on their practice of medicine. There is a need for national guidance on which procedures should be avoided by infected physicians. A professional association of eminence such as the AMA and/or the American College of Surgeons should form a high level task force to issue guidelines assessing the risk of HIV transmission during the performance of seriously invasive procedures. The issuance of clear guidelines would help set a uniform standard of practice across the country, reduce the burden on individual physicians and hospitals to make difficult assessments of risk, prevent inconsistent practice in different hospitals and geographic regions leading to loss of patient confidence, and reduce the possibility of legal liability for infected physicians and hospitals which countenance a continuation of seriously invasive treatment. The absence of prospective guidelines issued by the medical profession could well result in un-

desirable retrospective standards being laid down by the courts.

In *Doe v. Cook County Hospital*, United States District Court Judge John A. Nordberg required the signing of a consent decree to protect an HIV infected neurologist from unreasonable limitations placed on his right to practice.[29] Cook County Hospital has a policy of special monitoring of patients with HIV due to high case fatality, lack of effective treatment, the importance of preventive practices, the unique physical relationships between health care workers and patients; public trust in the hospital, and the right of the public to receive care without additional risk from the provider.[30] The physician agreed to special surveillance, to double glove before performing invasive procedures, and to not perform three procedures--muscle biopsy, sural nerve biopsy, and cerebral arteriography--which are formally a part of his credentialing, but which he had not performed in recent years. The judge held that future alterations in clinical practice could be permitted only if the physician poses "a significant health or safety risk to himself or others," and, except in an emergency, the neurologist must receive seven days notice of any alteration.

The Cook County Hospital case establishes the need for balance between a physician's rights and a patient's safety. Yet the concept of "significant risk" needs further clarification. Significant risk should be based on epidemiologic evidence of the gravity of the harm and the probability of it occurring. A risk is significant if: the mode of transmission is well established, even if the risk is small; the potential harm is serious; and the public health intervention is efficacious and does not pose disproportionate burdens on individual rights. Withdrawal of an HIV infected physician from performing seriously invasive procedures, provided the information can be kept confidential, does not pose an unbearable burden on the physician or the health care system. Reassignment to noninvasive procedures virtually eliminates any risk of harm.

The Cook County case also points up the futility of courts making a case-by-case determination of which medical procedures are sufficiently safe for an HIV infected physician to perform. It is not the proper function of the courts to list a detailed set of allowed and prohibited medical procedures. The court's decision simply underlines the need for forward-looking professional guidelines to assess which medical procedures pose a risk to the health of patients.

Screening of Physicians

If AMA ethical guidelines require a physician to refrain from performing certain seriously invasive procedures, would hospitals have an obligation to screen physicians? I do not accept that screening is a desirable or necessary result of a decision that HIV infected physicians should refrain from performing certain seriously invasive procedures. Screening of physicians has enormous professional, personal, social, and financial costs, similar to those previously discussed with patient screening: the potential for false positives, the cost of periodic retesting, the systematic collection of highly sensitive and confidential data, the potential for effectively ending the practice of trained and experienced physicians, and the constitutional ban to mandatory blood testing without reasonable cause. There are many well accepted situations in modern medicine where both legally and ethically it is advisable for physicians to inform their employers of their physical condition, but which do not mandate systematic screening. A surgeon with HBV, TB, or who is drug or alcohol impaired should not continue to practice without the hospital's knowledge and review. It does not necessarily follow, however, that all surgeons should be systematically screened for HBV, TB or drugs and alcohol. An assessment of any policy requires a balancing of the marginal public health benefit with the substantial costs of the policy to the practice of medicine.

Conclusion

The right to practice medicine and to receive medical treatment as a patient are both sufficiently precious to surround them with a panoply of legal protections. The respective claims of patients and physicians to know the serological status of the other significantly interfere with the other groups' rights to autonomy, privacy, and against discrimination. The very remote risk of transmission of HIV in health care settings does not justify the personally intrusive and financially costly programs of mandatory screening. A greater value of trust and communication between physician and patient is served by neither group asserting a right to coerce the other into testing their serological status.

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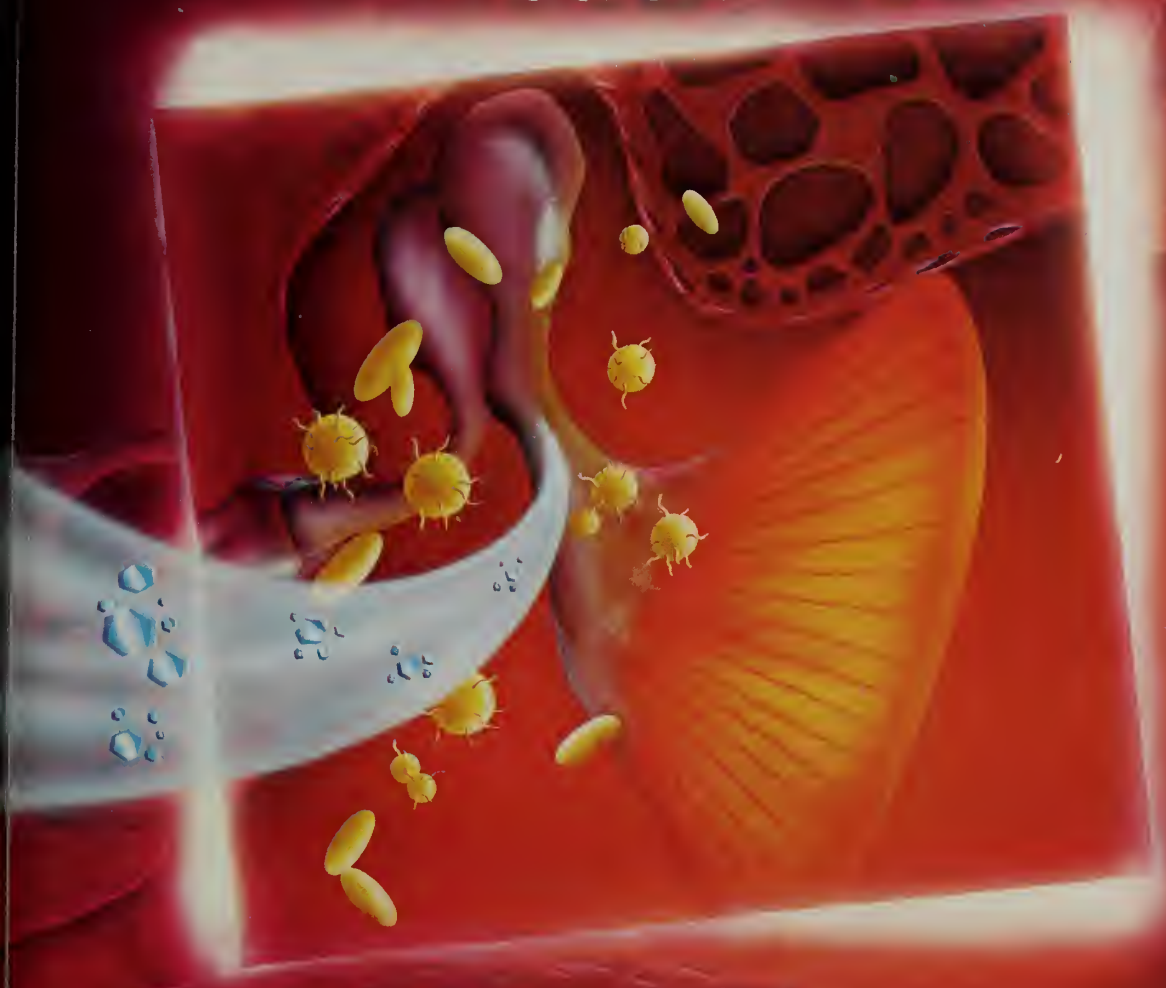

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BACTRIM SHOULD BE DISCONTINUED AT THE FIRST APPEARANCE OF SKIN RASH OR ANY SIGN OF AOVERSE REACTION. Clinical signs, such as rash, sore throat, fever, arthralgia, cough, shortness of breath, pallor, purpura or jaundice, may be early indications ot serious reactions. In rare instances a skin rash may be followed by more severe reactions, such as Stevens-Johnson syndrome, toxic epidermal necrolysis, hepatic necrosis or serious blood disorder. Perform complete blood counts frequently.

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PRECAUTIONS: *General:* Give with caution to patients with impaired renal or hepatic function, possible folate deficiency (*e.g.*, elderly, chronic alcoholics, patients on anticonvulsants, with malabsorption syndrome, or in malnutrition states) and severe allergies or bronchial asthma. In glucose-6-phosphate dehydrogenase deticient individuals, hemolysis may occur, frequently dose-related.

Use in the Elderly: May be increased risk of severe adverse reactions in elderly, particularly with complicating conditions, *e.g.*, impaired kidney and/or liver function, concomitant use of other drugs. Severe skin reactions, generalized bone marrow suppression (see WARNINGS and ADVERSE REACTIONS) or a specitic decrease in platelets (with or without purpura) are most frequently reported severe adverse reactions in elderly. In those concurrently receiving certain diuretics, primarily thiazides, increased incidence of thrombocytopenia with purpura reported. Make appropriate dosage adjustments for patients with impaired kidney function (see DOSAGE AND ADMINISTRATION).

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Information for Patients: Instruct patients to maintain adequate fluid intake to prevent crystalluria and stone formation.

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Pregnancy: Teratogenic Effects: Pregnancy Category C. Trimethoprim and sulfamethoxazole may interfere with folic acid metabolism; use during pregnancy only if potential benefit justifies potential risk to fetus. Nonteratogenic Effects: See CONTRAINDICATIONS section.

Nursing Mothers: See CONTRAINDICATIDNS section.

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Hematologic: Agranulocytosis, aplastic anemia, thrombocytopenia, leukopenia, neutropenia, hemolytic anemia, megaloblastic anemia, hypoprothrombinemia, methemoglobinemia, eosinophilia. *Allergic Reactions:* Stevens-Johnson syndrome, toxic epidermal necrolysis, anaphylaxis, allergic myocarditis, erythema multiforme, exfoliative dermatitis, angioedema, drug fever, chills, Henoch-Schoenlein purpura, serum sickness-like syndrome, generalized allergic reactions, generalized skin eruptions, photosensitivity, conjunctival and scleral injection, pruritus, urticaria and rash. Periarteritis nodosa and systemic lupus erythematosus have been reported. *Gastrointestinal:* Hepatitis (including cholestatic jaundice and hepatic necrosis), elevation of serum transaminase and bilirubin, pseudomembranous enterocolitis, pancreatitis, stomatitis, glossitis, nausea, emesis, abdominal pain, diarrhea, anorexia. *Genitourinary:* Renal failure, interstitial nephritis, BUN and serum creatinine elevation, toxic nephrosis with oliguria and anuria, crystalluria. *Neurologic:* Aseptic meningitis, convulsions, peripheral neuritis, ataxia, vertigo, tinnitus, headache. *Psychiatric:* Hallucinations, depression, apathy, nervousness. *Endocrine:* Sulfonamides bear certain chemical similarities to some goitrogens, diuretics (acetazolamide and the thiazides) and oral hypoglycemic agents; cross-sensitivity may exist. Diuresis and hypoglycemia have occurred rarely in patients receiving sulfonamides. *Respiratory:* Pulmonary infiltrates. *Musculoskeletal:* Arthralgia, myalgia. *Miscellaneous:* Weakness, fatigue, insomnia.

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Action: Yohimbine blocks presynaptic alpha-2 adrenergic receptors. Its action on peripheral blood vessels resembles that of reserpine, though it is weaker and of short duration. Yohimbine's peripheral autonomic nervous system effect is to increase parasympathetic (cholinergic) and decrease sympathetic (adrenergic) activity. It is to be noted that in male sexual performance, erection is linked to cholinergic activity and to alpha-2 adrenergic blockade which may theoretically result in increased penile inflow, decreased penile outflow or both.

Yohimbine exerts a stimulating action on the mood and may increase anxiety. Such actions have not been adequately studied or related to dosage although they appear to require high doses of the drug. Yohimbine has a mild anti-diuretic action, probably via stimulation of hypothalmic centers and release of posterior pituitary hormone.

Reportedly, Yohimbine exerts no significant influence on cardiac stimulation and other effects mediated by B-adrenergic receptors, its effect on blood pressure, if any, would be to lower it; however no adequate studies are at hand to quantitate this effect in terms of Yohimbine dosage.

Indications: Yocon® is indicated as a sympathicolytic and mydriatric. It may have activity as an aphrodisiac.

Contraindications: Renal diseases, and patient's sensitive to the drug. In view of the limited and inadequate information at hand, no precise tabulation can be offered of additional contraindications.

Warning: Generally, this drug is not proposed for use in females and certainly must not be used during pregnancy. Neither is this drug proposed for use in pediatric, geriatric or cardio-renal patients with gastric or duodenal ulcer history. Nor should it be used in conjunction with mood-modifying drugs such as antidepressants, or in psychiatric patients in general.

Adverse Reactions: Yohimbine readily penetrates the (CNS) and produces a complex pattern of responses in lower doses than required to produce peripheral a-adrenergic blockade. These include, anti-diuresis, a general picture of central excitation including elevation of blood pressure and heart rate, increased motor activity, irritability and tremor. Sweating, nausea and vomiting are common after parenteral administration of the drug.[1,2] Also dizziness, headache, skin flushing reported when used orally.[1,3]

Dosage and Administration: Experimental dosage reported in treatment of erectile impotence.[1,3,4] 1 tablet (5.4 mg) 3 times a day, to adult males taken orally. Occasional side effects reported with this dosage are nausea, dizziness or nervousness. In the event of side effects dosage to be reduced to ½ tablet 3 times a day, followed by gradual increases to 1 tablet 3 times a day. Reported therapy not more than 10 weeks.[3]

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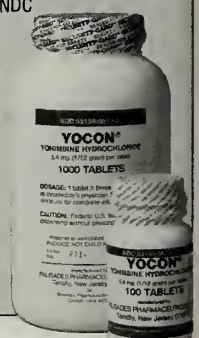

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ABORTION IN ADOLESCENCE: A CLINICIAN'S REFLECTIONS

Tomas J. Silber, M.D., M.A.S.S.

Introduction

There are about one million adolescent pregnancies every year in the United States. Two fifths of all American teenage females will have conceived by age 19 and half of these will deliver.[1] Adolescent pregnancy has great health, social, and political implications, relating to such issues as prematurity, low birth weight, infant mortality, learning problems, delinquency, poverty, and dependency.[2] And every year, approximately 350,000 teenagers choose to have an abortion.[3] The purpose of this paper is to highlight medico-legal issues of interest to physicians who encounter pregnant teenagers in their practice.

Adolescent Pregnancy and Abortion: Medical and Legal Aspects

The physician who diagnoses pregnancy in an adolescent will often be amazed by how late the patient comes for care. Indeed, minors are over represented among those who develop complications relating to late or absent prenatal care.[3] Teenagers are also major contributors to the statistics of second trimester abortions.[4] However, a teenage pregnancy carried to term still results in a higher mortality than an interrupted pregnancy through legal abortion.[5] The abortion mortality rate of adolescents is lower than that of their adult counterparts.[6] There is also a much higher death rate if one compares illegal abortion with legal abortion.[7]

Adolescents are less likely than older women to approve of abortion.[8] Healthy adolescent girls who choose abortion usually suffer transient behavioral difficulties. The experience of the procedure itself is considered stressful and associated with feelings of guilt and depression.[9] Disturbed teenagers may have a psychiatric breakdown after an abortion or delivery.[10] Despite these facts, the majority of teenagers who have undergone abortions agree that it was an important maturing influence in their lives.[10,11]

Legal issues relating to abortion remain under scrutiny and potential change, specific state rules need to be consulted periodically; in particularly difficult cases the aid of competent legal advice is recommended.[12-15] Rulings related to abortion in adolescence may be summarized as follows. In 1976, Planned Parenthood of Central Missouri v. Danforth stated that parents or guardians could not prevent an abortion of a consenting minor.[16] In 1979, the Supreme Court ruled that a Massachusetts law requiring parental consent for the abortion of an unmarried minor was unconstitutional. However, in that ruling the court allowed certain measures for the "immature minor"

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which encouraged parental consent and/or notification in those cases. Yet as a safeguard, the same decision allows for the required parental consent to be overruled by an appearance in court.[17] The issue is further complicated by limitations of access imposed by the federal government (denial of Medicaid payment for abortions).[18]

In medical practice, professionals holding honest positions, grounded in the best intentions, are nevertheless often engaged in angry battles in bitter opposing camps, regardless what the official position of their specialty, subspecialty, hospital, or institution may be. Those who invoke adolescent rights arguing strongly for adolescent autonomy in seeking medical care are primarily concerned that otherwise there could be a serious increase in adolescent morbidity and mortality as complications of sexually transmitted diseases, late diagnosis of pregnancy, late abortions, etc.[19] Those who favor focusing on parental control and responsibility insist on the value of acknowledging family autonomy and the special rights of parents to counsel and advise their children, attempting to "protect vulnerable, immature minors from the unforeseen consequences of their potentially irrational acts."[20]

A host of complex philosophical views have been advanced in order to analyze the moral significance of abortion in adolescence; their review goes beyond the scope of this article.[21] Recent technological advances have added a new dimension to this oldest of dilemmas.[22] It is suggested that a multidisciplinary approach may enrich the understanding of complex ethical issues.[23]

The debate surrounding pregnancy, sex education, adolescent contraception, and abortion can be viewed as part of a larger struggle in moral philosophy, political ideology, and socio-cultural development. Currently, our society stands at a crossroads at which a number of different ethical systems are converging. Each is a carrier of a highly particular kind of moral tradition. When such moral traditions encounter each other, they are to some large degree, hurt and fragmented in the process.[24] Thus, it is no surprise that the confusion inherent to pluralism is highlighted in issues dealing with the status of adolescents.

Discussion

In the national debate on teenage morality, abortion, and birth control, it appears that the farther away a theorist is from clinical reality the more clear cut and rigid are his viewpoints. Professionals from the various disciplines which are involved in the care of pregnant adolescents have repeatedly offered thoughtful advice.[25-27] In 1983, a hastily proposed and poorly researched solution to teenage pregnancy, the "squeal rule," was opposed by the vast majority of the medical community.

Recently, the National Academy of Sciences addressed the issue of adolescent pregnancy prevention.[28] Its panel on Adolescent Pregnancy and Childbearing called for "aggressive public education" and among other measures, supported widespread availability of oral contraceptives as the "safest and most effective means of birth control for sexually active adolescents."[28] It also advocated a greater distribution of condoms to teenagers, and emphasized sex education programs to include information on how to obtain these birth control products. Though the panel found "little available evidence" that programs to discourage teenagers from having sexual intercourse are working, it enforced further study of such programs. In brief, it outlined a program that requires greater support for low cost, convenient and confidential birth control services to teenagers, including public and private clinics, as well as additional effort to develop comprehensive school-based clinics. Finally, it proposed that should prevention efforts fail, abortion should be available as an option to adolescents without mandatory parental consent, but recommended that adoption also be a viable option.

At present, none can claim consensus; however, I propose that there are some shared concepts and understandings that may be considered congruent with commonly accepted practice, and which may serve as a basis for further actions.

- Efforts to persuade a pregnant adolescent that she should involve her parents in her medical care may be very beneficial. However, when this cannot be achieved, the adolescent should receive confidential medical care with the adult professional assuming a protective role.[19]

- Adolescents involved in reproductive decisions should receive individualized counseling. The adult professional community should be expected to offer guidance and support to teenagers during times of stress.[25]

- A pregnant adolescent has a right to elect to have an abortion, but states may impose some restraints on the exercise of this right.[29] Thus, a

state may require parental consent if it provides a judicial procedure as an alternative to consent. For this reason, physicians must periodically update their knowledge of the law in their own jurisdiction.

- Prevention of adolescent pregnancy and abortion is far from being a medical enterprise only, and requires involvement from all segments of society. "At the very least, teenagers should have as much knowledge of sex, as many good services available, and as many choices available as do adults."[30]

Conclusion

Controversy about abortion in adolescence will continue within the medical profession and in the broader society. It therefore becomes part of our task to help maintain the debate on a level of mutual respect and scientific accuracy, while also bringing knowledge and compassion to the teenagers and their families under our care.

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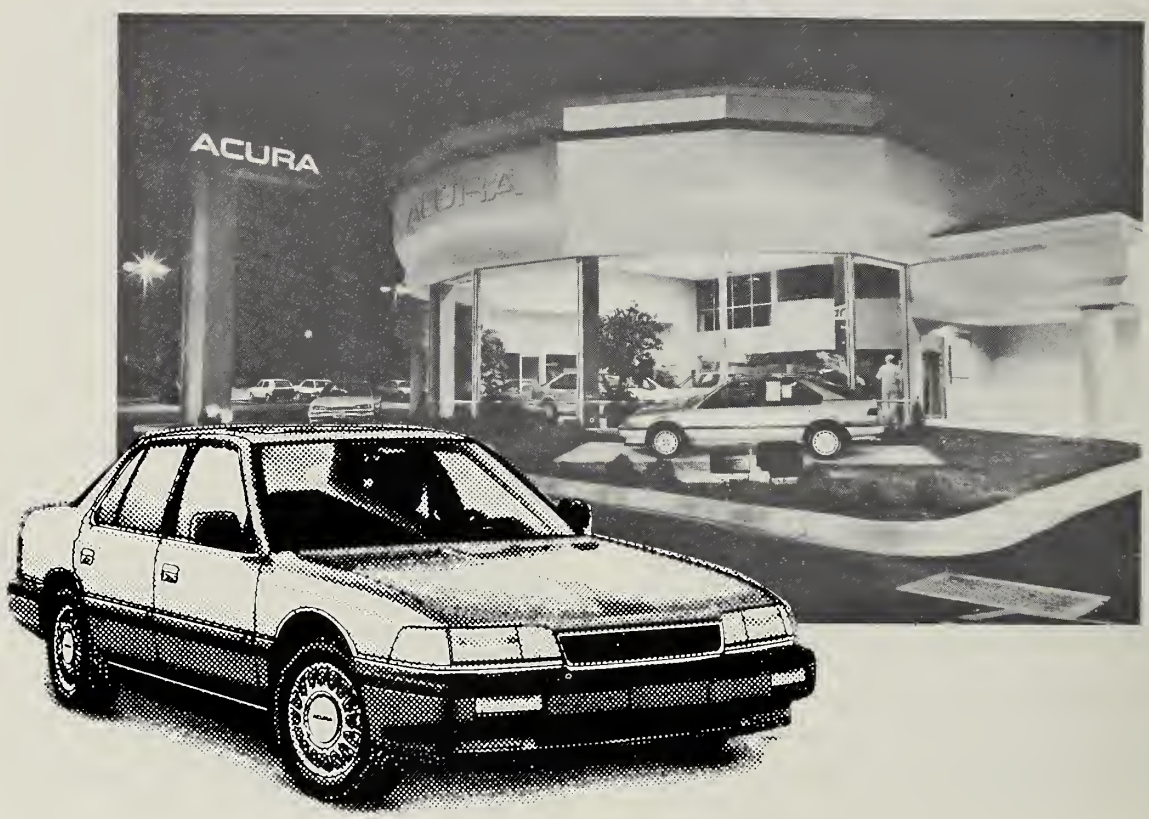

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MEDICAL ETHICS IN MEDICAL PRACTICE

Robert L. Perkel, M.D.

Introduction

Ethical issues abound in the arena of medical practice. Ethics is the science of morals; it is the department of study concerned with the principles of human duty, the moral principles by which a person is guided.[1] Moral issues are those concerned with virtue and vice, or the rules of right conduct.[1] Ethics is an attempt at a scientific approach, therefore, of the principles concerned with the rightness of human conduct. No area of medicine is devoid of potential ethical questions. Clinical practice requires the interaction of at least two human beings. Questions are raised; courses of action are contemplated; an ethical dilemma may ensue.

This review focuses on the application of medical ethics to medical practice. It is not a discussion concerning a particular ethical clinical dilemma but rather as a primer in approaching any or all biomedical ethics issues. The everyday nature of medical ethics questions is emphasized. A discussion of exactly what an ethical dilemma is then follows. The variety of practice settings in which ethical dilemmas are found is presented. The core of this paper then describes a method by which any biomedical ethics case may be analyzed. Finally, a basic ethics issue-oriented framework is listed in the hope that the reader will be challenged to attain a certain minimum competence in addressing the compelling ethical dilemmas in everyday clinical practice.

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Ethics and Everyday Medical Practice

There has always existed a tension between the physician's dual responsibilities: to the individual patient or practice and that to the larger society of which he is a member. This tension achieves a new dynamic with threatening epidemics, whether patient-activated (AIDS) or society-activated (nuclear weaponry). Cousins appreciated this tension a decade ago when he said, "ethical issues worth discussing are...ones that pertain to society as a whole...[as well as]...more immediate and traditional...patient-physician...problems."[2] The moral thrust of what most practicing physicians face concerns the rightness or reunions of ordinary, mundane decisions. Although the larger social questions are crucial for every citizen, including physicians, to ponder, they are not the focus of this discussion. Nor are the esoteric, special group questions the thrust here--it is a truism that special or unusual cases make bad ethics.

Where does our ethical thinking come from? What segment of our human experience influences physicians' approach to medical ethical issues? Pellegrino, et al, sampled over 1,000 recent medical school graduates and reported that in descending order personal values and beliefs, general clinical experience, interaction with peers, role model observation, family, ward

rounds, and reading were the most important factors influencing an approach to a medical ethical issue.[3] Doctors involved in patient care decisions every day apply the above list of factors, so that reasonable decisions may be reached. Cassell writes that four familiar considerations apply in almost any case: 1) indications for medical intervention; 2) patient preferences; 3) quality of life; and 4) external factors.[4] Everyday personal and clinical experience, therefore, forms the matrix upon which the above familiar considerations fit. Cassell rejects the notion that ethics is just common sense or a simple fix for difficult medical problems. However, the application of specific ethical principles to each medical dilemma may make it easier to attain an acceptable decision.

What is a Moral Dilemma?

If problems containing potential moral dilemmas abound in the everyday practice of medicine, it is important to define more precisely a moral dilemma. Beauchamp and Childress ask:

> What makes...any situation a moral dilemma...? In dilemmatic situations, the reasons on each side of a problem are weighty ones, and none is in any obvious way the right set of reasons....Moral dilemmas arise when one can appeal to moral considerations for taking each of two opposing courses of action.[5]

Dilemma, therefore, implies two potentially competing courses of action. Uncertainty is a recognizable clinical factor with which most physicians come to terms at some point in their careers. Doherty states that "ethical or moral certainty is so named because it is not absolute ...and...diametrically opposed...approaches...give rise to legitimate debate,"[6] thus underscoring the definition of dilemma with the concept of legitimately competing choices.

In a seminal paper, Kass wrote, "experienced physicians certainly need no introduction to...ethical dilemmas....They regularly confront concrete, troublesome, and often poignant dilemmas in their day-to-day practice."[7] Recognizing moral dilemmas should not be the problem in clinical practice; rather, it is, once recognition occurs, what the clinician does to resolve the dilemma. This resolution need not be the problem it is for many physicians if one orders an approach to these many, but often mundane, poignant dilemmas.

An ethical dilemma in health care often turns on the issue of "negative rights—the right that something not be done (ie, the patient's right to refuse therapy)."[8] It is important to include ethical dilemmas as well, in terms of positive rights—the right that something be done. The foundation of the clinical encounter is a specified body of knowledge and expertise that broadens our definition of dilemmas to include both negative and positive rights.

Practice Settings in Which Ethical Dilemmas Abound

There are a number of factors contributing to an increasing incidence in, or at least awareness of, ethical dilemmas in medicine. These factors may be divided into four larger realms: technology, autonomy, demographics, and the public nature of medicine. Technology needs no introduction to any physician practicing since mid-century. Intensive care units exist to promote life, often at the temporary (it is hoped) expense of perceived increased suffering. Technology is also expensive and creates other dilemmas of distribution. Autonomy, defined later, raises the spectre of consumerism and informed consent--many a physician looks back longingly on the paternalism of prior years. Demographics form an obvious and important factor with the geriatric imperative on one end of life and our technologic ability to create whole new ethical dilemmas in neonatal intensive care units at the other end of life. Finally, the public nature of medicine relates to the fact that what used to be nobody else's business (that which occurred between doctor and patient) is now everybody else's business.

It is difficult to envision a setting in which ethics does not play a role. No matter where a physician practices, ethical dilemmas exist. The intensive care unit and the hospital form the core of experiences rich in ethical quandaries, but office practice certainly contains an abundance of straightforward ethical case studies. Home care, long term care options such as nursing homes, and hospice and respite care also form an important bulwark of settings that create new sets of ethical questions in medicine.

Ethical Decision Making

If everyday medical practice is filled with ethical dilemmas confronting the practicing physician, and if the entire range of practice from intensive care unit to home care consists of med-

ical choices that often constitute competing ethical claims (therefore representing true dilemmas), then it follows that what the clinician requires is a moral reasoning guide to traverse the difficult terrain of biomedical ethical decision making. Beauchamp and Childress posit a four-tiered hierarchy to address moral reasoning:

4. Ethical Theories
↑
3. Principles
↑
2. Rules
↑
1. Particular Judgments and Actions[5]

Particular judgments and actions are made by individual clinicians making medical decisions every day, the ethical dilemmas that Kass declared experienced physicians confront on a daily basis.[7] These judgments are based on rules that have been developed from a multiplicity of sources. Beauchamp and Childress cite a useful example: the particular judgment may be that a physician tells the patient a difficult truth. The basis for that judgment is in the rule that it is wrong to lie to a patient. Rules, however, are based on principles, which are "more general and fundamental than moral rules and serve as their...source of justification."[5] The support for the moral rule that it is wrong to lie to patients may be found, for instance, in a larger principle of respect for persons, which defines the ethical principle of autonomy. Ethical theories form the largest overlay in this scheme, and represent "bodies of principles and rules" (examples of these are utilitarian and deontological theories). This paper will concentrate on the first three levels of interaction and not focus on the largest layer, which might be better suited for philosophical discussion than for medical decision making.

Biomedical Ethical Principles

The key to understanding the flow from individual clinical decisions that physicians make to the ethical principle that underpins individual decision lies in a delineation of the four basic biomedical ethical principles: 1) autonomy; 2) beneficence; 3) nonmaleficence; and 4) justice. It is useful to discuss each of these four principles and assign relative weight to how each is used in clinical practice.

Autonomy

Autonomy has emerged in the late twentieth century as the central tenet in medical ethics. Autonomy literally means self (*autos*) rule (*nomos*) and usually refers to the patient's being one's own unconstrained decision maker.[5] The patient's right to make decisions regarding treatment looms paramount in the writing of many major authors in the field of medical ethics. A recent Hastings Center publication states that autonomy is valued so greatly because it "reflects our society's long-standing tradition of recognizing the unique worth of the individual. We respect human dignity by granting individuals the freedom to make choices in accordance with their own values."[9] However, autonomy was not always the most important and most often cited principle for making medical-ethical decisions. Many physicians socialized at an earlier point of the century knew little of the autonomy principle in making clinical decisions. Even today, a well-represented minority opinion is that the hegemony of the autonomy principle has gone too far and that it represents an assault on basic medical values.[10]

Beneficence

If autonomy represents the prevailing principle governing medical-ethical decision making today, the second most important principle is that of beneficence. Beneficence is defined by the ordinary English meaning of the word: mercy, kindness, and charity.[5] "Doing good" is another way of explaining beneficence. Beneficence implies action on the part of the physician to prevent harm or remove harm; it provides for a positive action on the patient's behalf. Incorporated within the principle is the notion of physician paternalism with respect to the patient. Paternalism presupposes that the physician is making a benevolent decision for rather than with his patient. "Paternalism poses moral questions precisely because it involves the claim that beneficence should take precedence over autonomy."[5] Some physicians often use beneficence (and occasionally paternalism) as their paramount guiding principle. Paternalism has been ill-favored in recent biomedical ethical tracts, but it does have an important and time-honored role in doctor-patient interactions. Certainly few people quibble with the notion there is usually a confluence between wishes dictated by patient autonomy and actions directed by physician beneficence. The two principles are anything but mutually exclusive.

Nonmaleficence

The third biomedical ethical principle is known to every third year medical student by the admonition: "First, do no harm." Nonmaleficence means "one ought not to inflict evil or harm (what is bad)" while beneficence means "one ought to prevent evil or harm, remove evil, or promote good."[5] Nonmaleficence represents the absence of doing something, whereas beneficence requires action. Perhaps the clearest illustration of the difference between these two principles lies in the statement: "our duty not to push someone who cannot swim into deep water [nonmaleficence] seems stronger than our duty to rescue someone who has accidentally strayed into deep water [beneficence]."[5] A further requirement of nonmaleficence is that "agents be thoughtful and act carefully."[5] This requirement nicely complements notions of beneficence and autonomy so that physicians may be careful and thoughtful advocates of doing the right thing for patients (with patient concurrence).

Justice

The last of the four basic medical principles is the notion of justice. This implies a social network--it invokes doing something with respect to others. Justice goes beyond only the doctor and the patient, even if it is the doctor's taking into account other patients as he prepares to make an ethical choice for a particular patient. "Perhaps the concept most closely linked to justice in its broadest sense is desert (giving to each his right or due)."[5] Fairness and desert are the two concepts that best define the notion of justice. The term "distributive justice" is used to define "the justified distribution of benefits and burdens in society."[5] There are, of course, many different (and certainly no one, simple and correct) ways in which justice may be distributed. The variations are as endless as the human imagination, but the usual list of principles of distributive justice include: to each person an equal share; to each person according to individual need; to each person according to individual effort; to each person according to societal contribution; and to each person according to merit.[5]

Justice is closely linked to the notion of equity. The Hastings Center states that equity "pertains both to the individual patient's access to an adequate level of health care, and to the distribution of available health care resources. Justice demands that individuals have an opportunity to obtain the health care they need on an equitable basis."[9]

Ethical Case Analysis

Individual case discussions that arise in medical ethics can follow a set of guidelines, similar to a patient presentation with history, physical examination, assessment, differential diagnosis, and management plan. Any ethics case discussion should at least follow the outline below:

1. Gather the facts, assemble the data, ask all the questions needed in order to best accomplish information-acquisition.
2. Apply the ethical principles of autonomy, beneficence, nonmaleficence, and justice to all the facts of the case.
3. Weigh differing opinions (and ask for differing opinions) remembering that, by definition, an ethical dilemma exists when there are competing claims for the "right" action. Give weight to the various ethical principles regarding the particular case.
4. Formulate different solutions. How best does each potential solution seem to fit the case?
5. Finally, arrive at the one best solution in the particular case.

Proposed Basic Minimum Ethics Abilities

Ethical dilemmas have been defined and the many contexts in which they are found (hospital, office, home) have been explained. A process of making particular judgments has been linked to a knowledge and understanding of the four major ethical principles used in biomedical ethics. What should all of the foregoing allow the practicing physician to address? What should be a core, minimum body of knowledge that a clinician should possess in the application of ethical principles to clinical practice? A multiauthored special report posited a minimal basic curriculum so that a working knowledge of medical ethics would result.[11] An eight item scheme can be listed from this report:

1. The ability to identify the moral aspects of medical practice.
2. The ability to obtain a valid consent or a valid refusal of treatment.
3. Knowledge of how to proceed if a patient is only partially competent or incompetent to consent to or refuse treatment.
4. Knowledge of how to proceed if a patient refuses treatment.

5. The ability to decide when it is morally justified to withhold information from a patient.

6. The ability to decide when it is morally justified to breach confidentiality.

7. Knowledge of the moral aspects of the care of patients with a poor prognosis, including patients who are terminally ill.

8. Knowledge of issues in the equitable distribution of health care.

It is not the purpose of this paper to explore each of the above abilities so that the reader comes away with a practical and workable understanding of how to accomplish each of the stated goals. It is hoped, however, that an application of the material discussed herein, particularly the reaching of ethical decisions via the four large principles, will serve as a starting point for reaching comfortable decisions in this laudable basic curriculum.

Involving Others

Physicians need not feel they are alone in reaching ethical decisions regarding patients and health care issues. Just as each of us enjoys ready access to the informed medical consultations of our colleagues, we should feel comfortable in asking an extended list of colleagues for help in reaching consensus on ethical issues. Nurses are often in the best position to help guide us towards the correct ethical decision because they are so often most associated with the minute-to-minute needs of the patient. We are reminded of our "duty to consult and collaborate with colleagues so that the patient's autonomy, dignity, and best interests will be served justly and compassionately."[12]

Ethicists are playing an increasingly important role in many hospital settings--on the wards and in deliberations of hospital ethics committees. Ethicists should be used as consultants selectively and wisely.[13] Ethicists should not replace physicians as decision makers; they should serve as consultant experts to facilitate some of the difficult issues (remember, these may be mundane issues, nonetheless) facing clinicians. The other experts physicians ought to involve in ethical decisions include both hospital administrators and attorneys. Each brings a particular set of experiences to the clinical-ethical issue at hand. Each opinion is incorporated into a part of the whole. No one is in a better position to edit these opinions than the attending physician. Nothing should interfere with the primary function of the physician's fiduciary role towards his patients. The physician must first remain as the primary advocate for his patients' best interests.

Summary

Ethics should be considered a vital component of good clinical medicine. Clinicians should be at the center of the ethical debates and dilemmas in medicine. This should certainly not be left to the ethicists, attorneys, nurses, or hospital administrators. However, each of these individuals has important contributions to make to each biomedical ethical decision. Ethical issues sometimes seem very straightforward and at other times appear very complex. However, the crucial ethical-medical dilemmas are not the sensationalistic cases but rather the mundane, everyday experiences that comprise clinical practice.

The terrain of today's ethical medical dilemmas include the hospital, the office, long term care facilities, and the patient's home. The myriad of clinical situations and problems is less important than a coherent, ordered approach to every ethical dilemma. Clinicians should have a working knowledge of the ethical framework for clinical decision making. This ethical framework includes principles of autonomy, beneficence, nonmaleficence, and justice. The paramount operative ethical principle today is that of respect for patient autonomy. Although individual cases have unique properties, we should attempt to find how these principles apply in each case. An eight item scheme regarding basic abilities in medical ethics has been proposed. This should serve as a basis for clinician involvement in daily ethical issues.

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ETHICAL CONSIDERATIONS IN SOLID ORGAN TRANSPLANTATION

John Noseworthy, M.D.

Since the first successful human solid organ transplant more than 25 years ago, permitting an identical twin to cure renal failure in his sibling with the "gift of life," the application of this modality of medical treatment has proliferated enormously--and with it the demands for close examination of the ethical considerations surrounding this aggressive technology. It is unlikely that the transplant group in Boston who harvested the twin's kidney and grafted it to another could have foreseen the techno-ethical imbalance which the subsequent broad application of such life-saving therapies would engender. With the persisting efforts in immunomodulation from azathiaprine to thoracic duct drainage to antilymphocyte sera, now culminating in cyclosporine and monoclonal antibodies, the initially amazing technical feats of heart and liver transplants have now become so frequently performed as to seem commonplace. One can readily speculate that as more "experimental" forms of solid organ replacement such as pancreatic and small bowel become refined, the pressures for society's ethical perspectives to keep pace with the rapidly-advancing technology of such complex medical/surgical intervention will continue to escalate. As increasing numbers of patients with end-stage organ failure emerge as candidates for organ replacement and as more organ systems become amenable to replacement *in toto*, the demand for organs for transplantation will outstrip supply even more dramatically than it does today.

The current rates of long term graft survival--and thus patient survival--that follow renal, heart, and liver transplants, coupled with the dramatic improvement in quality of life that transplantation makes possible, have clearly catapulted organ transplantation well ahead of alternate therapies for end stage organ system failure. No longer is it reasonable to consider long term dialytic therapy as the mainstay treatment for renal failure unless specific contraindications to surgery are present. Essentially all end stage renal disease patients should be evaluated for transplantation. When coupled with a quality of life after transplantation which rivals that before the development of organ failure, the course is clearly set which forces us to do everything we can to diminish waiting lists and increase donor organ availability.

Although expensive, the amazing transformation that liver transplantation can bring to the life of a young child ravaged by the consequences of biliary atresia, forces us to look beyond the patient's personal economic resources and beyond our own emotional constraints. Both the medical and lay society of today have the responsibility thrust upon them by this therapeutic modality to keep "dealth on the waiting list" from becoming an increasing reality.

The cost of these forms of treatment is great. Our government's expenditures for the end stage renal disease program is enormous--so great, in fact, that some believe they should be curtailed, and many would do what they can to prevent a similar economic commitment from being established for liver and/or heart disease treatment programs.

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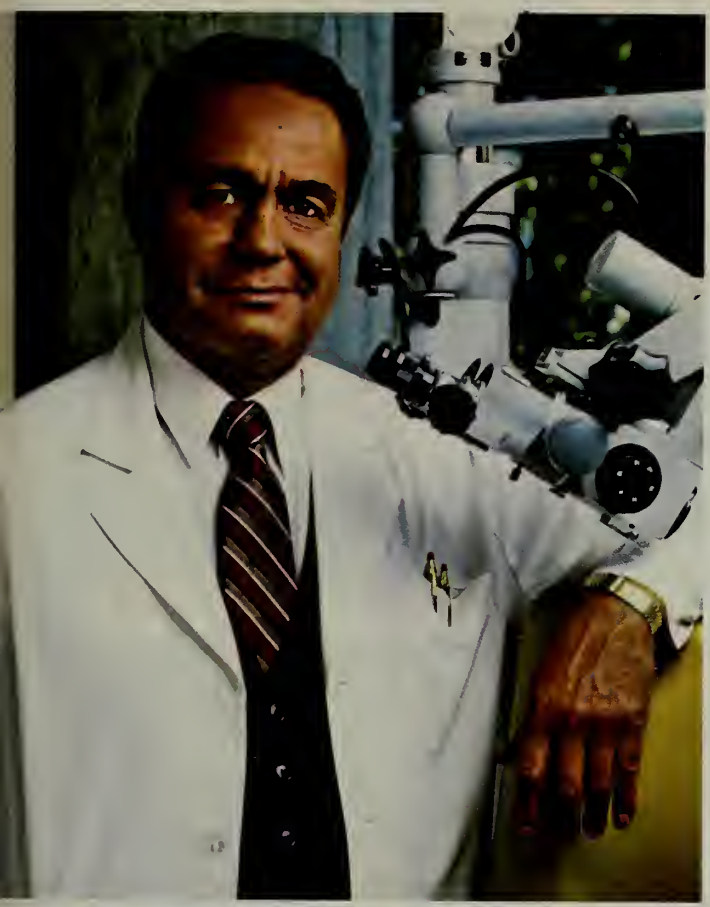
But the reality is clear. Treatment of end stage organ failure with transplanted organs is a therapeutic option that must be more widely considered day by day. Thus, the ethical positions of both physicians and the public (as well as the bill payers, ie, all of us) must be shaped to allow application of this treatment to all who need it.

Ethics has always been an inherent element in the professional life of the physician. We have always been committed to striving to find the right course of action for our patients--to restore function and life, to lessen suffering, to improve the quality of existence. These considerations are inherent to the art and science of healing. As the primary patient advocate, we have always been attuned to these issues. It seems, however, that the increasingly complex multispecialty health care environment in which we find ourselves today has greatly exacerbated the difficulties encountered when we try to work through the treatment options available for our patients. We find our decisions in this regard subjected to intense and broad public scrutiny, often by parties we view as interlopers. Our decisions, guided by our ethical commitment to our patients, often are made to seem self-serving or shallow by "self-acclaimed" pundits acting as medical care critics. As advocates of organ transplants, we must be willing to do battle in this public setting if we are to fulfill our inherent obligations to our patients and their families. We cannot forgo the involvement. We must become participants in the processes of ordering the need and distributing the resources for solid organ transplants.

Support for our position as ethical advocates as well as health care advocates for our patients derives from the long history of the healing arts. Additionally, many systems of ethical thought provide organized considerations of these matters and can clearly be applied to the quandaries raised when we attempt to order the need for transplantation and distribute these increasingly scarce health care resources. These principles of ethics, cutting across several systems of ethical thought, are applicable to these dilemmas. Beneficence, autonomy and justice, when applied to this area of difficult clinical decision making, may not eliminate the soul-searching that we physicians must do, but they do provide several guiding concepts that aid in arriving at a conclusion which balances patient needs and desires with those of society at large.

Beneficence is the inherent quality of the physician's commitment to *do good* for his patients. It is the cornerstone of the ethical healing arts. It pushes us as physicians to make those decisions and recommendations for therapy which will improve the quality and quantity of life for those who seek our skills. Autonomy prompts us to give merit to the rights of our patients to make their own choices about treatment options. It urges us to see their own point of view and to put ourselves in their places. It directs us to take their part. Justice instructs us to take a broader view of our recommended course of treatment--to put it into a societal context so that all those who need care obtain it in a balanced, responsible way. It forces us to take into consideration what is best for the greatest number as well as protecting the rights of those members of society not in need of direct care but who must participate in care giving by supplying resources that make treatment possible. Application of these principles to the difficult questions raised by solid organ transplantation may help our profession guide society in developing the cooperative programs at local, state, regional, national (and even international) levels which will provide the appropriate distribution of transplantation resources.

Although clearly established on a long term basis as an effective and accepted modality of treatment for end stage renal disease, renal transplantation continues to raise ethical issues for both practitioners and the public at large in several areas. Highest on this list of unresolved issues is the continuing short fall of available donor organs. Recent Gallup polls continue to define an unacceptable level of apathy among the general public. Despite believing that renal transplants are a good thing and accepting organ donations as a positive societal act, a majority of the populace still holds to a position of apathy when it comes to actively participating in donor recruitment programs. They view organ donation as "a good idea for 'them,' but not for me." Thus, educational programs directed at the public must evolve which more effectively stimulate broad participation in donor recruitment if the demand/supply imbalance is to be overcome. This dilemma has given rise to legislative action focusing on "required request" mechanisms. These mandates, although potentially awkward for the physician and the health care deliverer, are just



Dr. Tipton and residents examining post-operative patient in recovery room.

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Drug Interactions—No interactions have been observed between Axid and theophylline, chlordiazepoxide, lorazepam, lidocaine, phenytoin, and warfarin. Axid does not inhibit the cytochrome P-450-linked drug-metabolizing enzyme system; therefore, drug interactions mediated by inhibition of hepatic metabolism are not expected to occur. In patients given very high doses (3,900 mg) of aspirin daily, increases in serum salicylate levels were seen when nizatidine, 150 mg b.i.d., was administered concurrently.

Carcinogenesis, Mutagenesis, Impairment of Fertility—A two-year oral carcinogenicity study in rats with doses as high as 500 mg/kg/day (about 80 times the recommended daily therapeutic dose) showed no evidence of a carcinogenic effect. There was a dose related increase in the density of enterochromaffin-like (ECL) cells in the gastric oxyntic mucosa. In a two-year study in mice, there was no evidence of a carcinogenic effect in male mice; although hyperplastic nodules of the liver were increased in the high dose males compared to placebo. Female mice given the high dose of Axid (2,000 mg/kg/day, about 330 times the human dose) showed marginally statistically significant increases in hepatic carcinoma and hepatic nodular hyperplasia with no numerical increase seen in any of the other dose groups. The rate of hepatic carcinoma in the high dose animals was within the historical control limits seen for the strain of mice used. The female mice were given a dose larger than the maximum tolerated dose, as indicated by excessive (30%) weight decrement compared to concurrent controls, and evidence of mild liver injury (transaminase elevations). The occurrence of a marginal finding at high dose only in animals given an excessive, and somewhat hepatotoxic dose, with no evidence of a carcinogenic effect in rats, male mice, and female mice (given up to 360 mg/kg/day, about 60 times the human dose), and a negative mutagenicity battery is not considered evidence of a carcinogenic potential for Axid.

Axid was not mutagenic in a battery of tests performed to evaluate its potential genetic toxicity, including bacterial mutation tests, unscheduled DNA synthesis, sister chromatid exchange, and the mouse lymphoma assay.

In a two-generation, perinatal and postnatal, fertility study in rats, doses of nizatidine up to 650 mg/kg/day produced no adverse effects on the reproductive pertormance of parental animals or their progeny.

Pregnancy—Teratogenic Effects—Pregnancy Category C—Oral reproduction studies in rats at doses up to 300 times the human dose, and in Dutch Belted rabbits at doses up to 55 times the human dose, revealed no evidence of impaired fertility or teratogenic effect; but, at a dose equivalent to 300 times the human dose, treated rabbits had abortions, decreased number of live fetuses, and depressed fetal weights. On intravenous administration to pregnant New Zealand White rabbits, nizatidine at 20 mg/kg produced cardiac enlargement, coarctation of the aortic arch, and cutaneous edema in one fetus and at 50 mg/kg it produced ventricular anomaly, distended abdomen, spina bifida, hydrocephaly, and enlarged heart in one fetus. There are, however, no adequate and well-controlled studies in pregnant women. It is also not known whether nizatidine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Nizatidine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers—Nizatidine is secreted and concentrated in the milk of lactating rats. Pups reared by treated lactating rats had depressed growth rates. Although no studies have been conducted in lactating women, nizatidine is assumed to be secreted in human milk, and caution should be exercised when nizatidine is administered to nursing mothers.

Pediatric Use—Safety and effectiveness in children have not been established.

Use in Elderly Patients—Ulcer healing rates in elderly patients are similar to those in younger age groups. The incidence rates of adverse events and laboratory test abnormalities are also similar to those seen in other age groups. Age alone may not be an important factor in the disposition of nizatidine. Elderly patients may have reduced renal function.

Adverse Reactions: Clinical trials of nizatidine included almost 5,000 patients given nizatidine in studies of varying durations. Domestic placebo-controlled trials included over 1,900 patients given nizatidine and over 1,300 given placebo. Among the more common adverse events in the domestic placebo-controlled trials, sweating (1% vs 0.2%), urticaria (0.5% vs <0.01%), and somnolence (2.4% vs 1.3%) were significantly more common in the nizatidine group. A variety of less common events was also reported; it was not possible to determine whether these were caused by nizatidine.

Hepatic—Hepatocellular injury, evidenced by elevated liver enzyme tests (SGOT [AST], SGPT [ALT], or alkaline phosphatase), occurred in some patients possibly or probably related to nizatidine. In some cases, there was marked elevation of SGOT, SGPT enzymes (greater than 500 IU/L), and in a single instance, SGPT was greater than 2,000 IU/L. The overall rate of occurrences of elevated liver enzymes and elevations to three times the upper limit of normal, however, did not significantly differ from the rate of liver enzyme abnormalities in placebo-treated patients. All abnormalities were reversible after discontinuation of Axid.

Cardiovascular—In clinical pharmacology studies, short episodes of asymptomatic ventricular tachycardia occurred in two individuals administered Axid and in three untreated subjects.

Endocrine—Clinical pharmacology studies and controlled clinical trials showed no evidence of antiandrogenic activity due to Axid. Impotence and decreased libido were reported with equal frequency by patients who received Axid and by those given placebo. Rare reports of gynecomastia occurred.

Hematologic—Fatal thrombocytopenia was reported in a patient who was treated with Axid and another H_2-receptor antagonist. On previous occasions, this patient had experienced thrombocytopenia while taking other drugs.

Integumental—Sweating and urticaria were reported significantly more frequently in nizatidine than in placebo patients. Rash and exfoliative dermatitis were also reported.

Other—Hyperuricemia unassociated with gout or nephrolithiasis was reported.

Overdosage: There is little clinical experience with overdosage of Axid in humans. If overdosage occurs, use of activated charcoal, emesis, or lavage should be considered along with clinical monitoring and supportive therapy. Renal dialysis for four to six hours increased plasma clearance by approximately 84%.

Test animals that received large doses of nizatidine have exhibited cholinergic-type effects, including lacrimation, salivation, emesis, miosis, and diarrhea. Single oral doses of 800 mg/kg in dogs and of 1,200 mg/kg in monkeys were not lethal. Intravenous LD_{50} values in the rat and mouse were 301 mg/kg and 232 mg/kg respectively.

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one way in which a strong ethical position can be taken which has the power to effect a change in organ availability, while at the same time lessening some of the ethical conflicts of interest to which scarce donor resources may give rise. Certainly the medical profession decries the concept of the sale of body parts. The ethics committee of the Transplantation Society has taken a strong and definitive stand in opposition to this suggested source of donor material--one that emphasizes the extraordinary magnitude of the *gift* of a donor organ and supports a neutral, objective and balanced view of assignment of need as a method of organ distribution. But the pressures can be great. They force us to take active steps to support these measured actions which will provide equitable and caring procurement and distribution of kidneys for transplantation so that an ethical basis of patient care can be maintained.

We must each be willing to participate in donor recruitment within our institutions of practice whenever we can. We must be willing to provide comfort and support for our patient's family and help allow the positive experience of organ donation--as emotionally awkward for us as the occasion may be--to be a positive and healing (thus ethically sound) act for the grieving family. Other issues relating to donor organ lack of availability have emerged to challenge our ethics of care. Some decry the use of living related (or unrelated) donor material in a time when improved immunosuppressive regimens have led to constantly-increasing rates of survival for cadaver organ transplants. Should the risks to the living donor be eliminated? Or should a broader source of living donors--those unrelated to the patient but with strong emotional commitments--be used in order to lessen the gulf between the short supply of kidneys and those who need them. For children awaiting renal transplantations whose duration of end stage disease exacerbates every adverse aspect of their failing health, the use of parental or non-minor sibling living related grafts is frankly too appealing and appropriate to be ignored. With careful, objective counseling and medical/surgical management of the prospective donor, this source of graft material continues to be widely used and highly acceptable--both physiologically, immunologically, and ethically.

Another source of donor organs, particularly relevant to pediatric renal transplant considerations, which presents us with a profound ethical challenge, is that of anencephalic donors. This topic is a complex one, but as a transplant surgeon who has harvested and engrafted anencephalic kidneys in the past, I believe it is one that must be given serious and thoughtful reconsideration so as not to discard, for emotional reasons, a potentially beneficial source of donor organs which can alleviate suffering for both the recipient as well as the donor family. Perhaps as Dr. Michael Harrison and others have suggested, anencephaly required a new definition with the concept of brain-absence replacing our current brain death criteria for this unique biologic state.

In no area of solid organ transplantation do the considerations of alternative donor sources have more vital application than in the area of hepatic transplantation in young children and infants with biliary atresia. These very sick babies, stunted by chronic hepatic failure and in need of early transplantation, constitute a pool of recipients for whom few donors of appropriate size/match exist. Here, death on the waiting list is a reality, and no individual national media plea by a family can solve the growing problems that this group of patients presents. As discussions evolve suggesting that these patients be treated primarily with hepatic transplantations, foregoing the usual efforts at biliary tract reconstruction, the pressure for more and younger hepatic donor sources is certain to increase dramatically. Although this approach is not yet advocated explicitly, its potential certainly underscores the ethical dilemma posed by these children. Are anencephalic donors a potential source of hepatic grafts for these babies? Or will the technology of reduced hepatic grafts--segments of liver from cadaver organs of larger donors--allow size-tailoring of tissue which will permit these small recipients to receive part of an organ from a donor otherwise too large to be applicable? These procedures increase risk, time, and expense, but do offer some hope of being one possible solution to the ethical bind these children present us.

The moderately successful application of reduced-size donor organs in hepatic transplantation has been documented in a limited number of young recipients by Dr. Christoph Broelsch and his colleagues at the University of Chicago. The success rates for this technique are not as gratifying as for size-matched whole organ grafts but

many factors may be involved in this less-than-optimal outcome. Most of these efforts are undertaken for patients with hard-to-manage hepatic failure who have been on the waiting list for a protracted period of time and whose condition of progressive deterioration forces consideration of such higher-risk and more aggressive treatment options. The ethical challenge inherent within this setting stems from the reality that each such reduced size graft uses up an organ of a size more compatible with a less-urgently sick larger (often adult) recipient. If such reduced-size grafts carry a higher risk for failure, necessitating repetitious sequential grafts to treat primary graft non-function, are we locking ourselves into a demanding cycle of care that ultimately depletes the already-compromised donor pool? Such challenges to reduced-size hepatic grafts are being raised and do have merit. But if these techniques can be improved (as I am certain they will), they offer the hope of truly expanding the available pool of donor liver tissue by potentially allowing one donor to supply grafts for multiple recipients--using segments of the donor organ tailored to the size needs of several hosts. Thus, a technique which from one perspective may be ethically unappealing has the real potential to alleviate a truly taxing ethical situation. Ultimately, such segmental grafts may lead to the use of living-related hepatic transplants in which a segment or lobe of liver is harvested from a live donor in an elective setting. Certainly, such considerations are currently speculative, but they do help to illustrate some of the potential ethical conundrums which will undoubtedly emerge from this expanding technology.

As the ethical complexity of such transplants considerations proliferate, our profession and its health care institutions must equip themselves with the modalities and structures for dealing with these problems of ethical health care decision making. One such mechanism is the institutional Biomedical Ethics Committee. Such groups of concerned health care professionals (and lay members) can perform crucial services to the transplant team and its endeavors. They can provide advisory evaluation of treatment options such as the use of anencephalic donors. They can serve as an educational resource for the hospital, bringing together objective data from disparate sources to provide a balanced and ethically-oriented view of multiple treatment alternatives. They can be an organizational resource for their institution, making their staff and physicians aware of local and regional resources available for the treatment of such complex patients. These groups should emphasize advice and education, using their broad perspective and ethical orientation as a consultative service for those physicians delivering the front-line care.

Those in the trenches must be willing to use such group resources so that the broadest, most balanced ethical view possible may be derived. Often the diversity of perspective these committees provide is a great help in resolving the conflicts that arise when beneficence, autonomy, and justice are concurrently brought to bear on issues of distribution of organ transplantation resources. They can play a vital part in "ordering the need" and aiding the transplanter in deciding who gets the scarce resource.

Finally, those of us involved in solid organ transplantation must give consideration to two pivotal practical issues which cut across all ethical aspects of these treatment modalities: where should it be done (and by whom); and who pays for doing it? Should we leave the answers to these questions to the current highly competitive health care marketplace? Is it enough to have the necessary team to supply the technology? Some would argue that the high risks involved coupled with the demand for volume-generated skill and competence demand external regulation with establishment of restricted centers at which such transplant activities would be focused. Some states have taken steps to establish regional centers where minimal-volume transplantation activities will be fostered. Similar proposals are being considered at the national level as well. These programs may maximize statistical success, but will they unduly stress families with travel and separation pressures, compromising the ultimate good that is done?

Intimately linked to these concepts of regional centers of solid organ transplantation activity is the issue of funding. Keeping pace with our rapidly advancing transplantation technology is a costly undertaking. Does it force us to spend funds on a relatively small sector of the population, thus using up monies that might better be applied to a wider range of disease prevention programs affecting a larger segment of the population? Again, a spectrum of options have been used to provide funding. In Ohio, the Commis-

sioner of Health has put in place a system of payment to provide solid organ transplant care for any state citizen needing such care, regardless of their personal financial resources or the availability of health insurance. Coupled to this "guaranteed transplant care" is a program of regionalization of such activities, with four centers in the state approved to provide extra renal solid organ transplantation services, and ultimately contributing funding for those without resources. Will such a program find broad utility beyond a single state? Is this a model for a national program?

At another point along the spectrum, some transplant centers have not chosen to use public funds, however derived, in order to finance organ grafting, but have asked for up-front self-payment before such treatment will be undertaken. Widespread local and regional private sector fund raising has frequently arisen in response to individual family appeals for aid, thus filling the gap between the high costs for treatment and the limited resources of many of the patients in need. It has been gratifying to see that as hepatic transplantation evolved from the realm of an experimental procedure to the focused reality of accepted therapeutics, some private third-party health insurers have organized plans which provide financial resources for these high cost modalities of care. As the incidence of these procedures increases and as the scope of solid organ transplantation broadens to include pancreatic and small bowel transplants (as just two examples), will these sources of private sector funding keep pace with the rapidly growing demand for funding? Or will other options, such as national catastrophic health insurance evolve to fill the gap?

The ultimate ethical consideration in the realm of solid organ transplantation is not the short term consideration on which we have been focusing, but rather the long term commitment to continued expensive and potentially complicated immunomodulation that is at the heart of the recent high success rates surrounding organ grafts. Liver transplantations, although begun on a clinical experimental basis in the early 1960s, did not achieve appropriate long term success until the availability of cyclosporin A in the late 1970s. Heart transplantation was likewise limited by its low success rates to only one or two centers until the same immunosuppressive agent was used. Continued use of these transplant modalities necessitates the ongoing use of this drug and commits the patient to its daily use and to its continuing expense. With an annual cost of between $5,000 and $8,000 for maintenance immunosuppression, we have accepted a continuing demand for high cost health care. And yet neither we as care providers, nor the patient really have a choice. The transplant necessitates the medicine, and we cannot turn away from our commitment to provide the needed combination. As other agents for immunosuppression are developed, there may be some hope of diminishing the absolute costs of this long term maintenance care, but even long-acting agents bespeak the need to consider solid organ transplantation as a chronic disease. As such, the patient continues at risk for complicated interventions and for the potential of retransplantation when chronic graft dysfunction occurs.

Thus, we are sharply focused on the ultimate image of the ethics of solid organ transplantation. It is mandatory that we give complete and thorough considerations of both the short and long term aspects of this treatment for end stage organ failure when we initially recommend it. We must understand the long term commitment of care which it entails. We must be willing to accept the long term costs associated with it and to make available to the patient those resources which are required for a successful long term outcome. We must be meticulous in defining the potential hazards and the life long care that is needed so that the patients and their families will understand as fully as possible what is in store for them. We must allow a balance between our own desires for beneficence in the care of our patients requiring organ grafts and the patient's rights to autonomy. But we must not fail to do this within the arena of justice--so that our individual patient recommendations will take into consideration the role of society in providing essential support for these dramatic and costly health care options.

The ethical challenges in the realm of solid organ transplantation are great. Some of their specific aspects have been discussed. It appears that no one solution is necessarily correct for all patients in need of these therapies, but some suggestions and challenges for their resolution have been put forth. It is incumbent upon those of us involved in providing these complex health care resources to do so in as ethical a way as possible,

ultimately balancing our own desires as physician to do good to and for our patients, and to provide them with the freedom to participate intelligently in deciding among their health care options, with a broadly responsible view of health care which permits a fusion of the individual and group desires for successful and ethically appropriate solid organ transplantation programs.

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Religious Perspectives

A CATHOLIC PERSPECTIVE ON RELIGION AND ORGAN TRANSPLANTATION

Thomas R. Ulshafer, S.S., Ph.D.

Introduction

Organ transplantation has become almost commonplace in recent decades and this has raised many moral issues for Catholic thinkers. Some of these are new; others are old issues with new urgency. Some of these issues are deeply personal; others are more properly matters for the makers of public policy. This brief article cannot offer positions on all of these issues, even the most important.

The focus here will be on two questions only, both of which are concerned with the supply of organs for transplantation. The first issue is, on what basis may a person decide to donate an organ (while that person is still alive) for the benefit of someone else? This issue was debated by Catholic ethicists from the mid-1940s to the mid-1960s, and a review of the controversy offers a good look at how Catholic medical ethics developed its basic stance toward the issue of organ transplantation. The second issue is, assuming that donating organs for transplantation is a good thing to do, what is the proper role of government in the task of organ procurement? This issue will continue to preoccupy Catholic moralists and others as public policy in this area becomes more aggressive.

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The Ethics of Organ Donation *(inter vivos)*

From today's vantage point, this may not look like an issue worth debating, but for the Catholic medical ethicist of 30 years ago, this was *the* issue regarding organ transplantation. To understand how this could have been so, it is necessary to grasp some background.

In traditional Catholic medical ethics, the removal of an organ from a living person was spontaneously classified with other surgical procedures under the general topic of "mutilation" of the body. Since physical life, and so the body itself, were seen as gifts entrusted to the human person by a loving Creator, no one would have the right to jeopardize or mutilate the body without sufficient reason. Normally such a reason could be found in an anatomical reading of the so-called principle of totality; ie, the organ (the part) may be sacrificed for the sake of the whole body (the totality).

This principle has had a long history and had been used widely in Catholic medical ethics. For writers of the '40s and '50s, *the* authoritative statement of the principle was to be found in the 1930 encyclical letter of Pope Pius XI, "On Christian Marriage."

> Private individuals. . .are not free to destroy or mutilate their members, or in any other way render themselves unfit for their natural func-

tions, except when no other provision can be made for the good of the whole body.[1]

In light of this principle, it is easy to see why most Catholic ethicists at one time disapproved of taking healthy organs from healthy donors: the excision was not for the sake of the *donor's* health![2]

A minority of Catholic thinkers developed a more creative alternative. This approach consisted of both a reinterpretation of the principle of totality and the introduction of a second moral principle into the assessment. They began by noting that the Catholic Church had not objected to such procedures as skin grafts and blood transfusions, even though in most cases these were not done for the sake of the donor. Might this not indicate, for one thing, that avoiding *physical* mutilation itself is less important than retaining *functional* integrity? And so these thinkers began to interpret the principle of totality in a less physical and less restrictive manner. (Different thinkers carried this reinterpretation to different lengths.)

It was the early introduction of a second moral principle, however, that eventually caused the real breakthrough.[3] The idea was that the issue should not only be viewed under the paradigm of mutilation but should also be seen as a taking of risks in order to help another in need. That is, organ donation is less like an appendectomy and more like a Caesarean section for the sake of an unborn child or a perilous rescue of a drowning ice skater. The primary principle at stake in such cases is that of love, or Christian charity.

But two obstacles remained. First, how does one understand this second principle, that of love, so that it gives a person an unlimited right to dispose of his/her own life and health for the good of another; ie, to commit altruistic suicide? And the second obstacle was that organ donation (*inter vivos)* was still not approved in official Catholic teaching.[4]

Some ethicists overcame the first obstacle by presenting the principle of totality as a limit on the principle of charity. In other words, a donor has God-given duties to self (and, we may add, to others) which are not annulled by the intention of doing good for a potential recipient. The second obstacle was finally overcome for Catholics in the U.S. when their bishops wrote in 1971:

> The transplantation of organs from living donors is morally permissible when the anticipated benefit to the recipient is proportionate to the harm done to the donor, provided that the loss of such organ(s) does not deprive the donor of life itself nor of the functional integrity of the body.[5]

The Politics of Organ Procurement

Since the 1960s, there have been important developments in medicine and in law which have refocused the discussion regarding organ transplantation. Better knowledge of organ rejection has made it less important to seek donors from among relatives of potential recipients. New techniques for harvesting and preserving organs and the legal acceptance of brain death have enabled medicine to put more emphasis on the cadaver as a source of needed organs. The graduation of many forms of organ transplantation from experiment to treatment has raised increasing concern about the limited supply of suitable organs. Within this climate of increasing demand, it has become attractive to turn to government for solutions.

Catholics could easily tend to be cautious about this last trend, based on a convergence of several traditional lines of argument. First, the Catholic Church has been a strong supporter of the requirement of consent in medical matters in general and in the decision to donate organs in particular. As we saw above, while it may be a good thing to donate an organ, it is not a duty; and no one, including civil authority, has a right to demand such a sacrifice.

Second--and this builds on the first point--the Catholic Church has a tradition of reverence for the human body after death. Even when discussing the possibility of donating organs from a cadaver or performing an autopsy, traditional Catholic ethicists required that normally consent should be given by the responsible party.[6]

Third, the principle of totality was not applied to the relationship between the individual and society. That is, the person or his body were *not* viewed as parts of the state in the same way that limbs were seen as parts of an individual's body. And so, it would not be right for the state to confiscate or commandeer body parts as needed for the welfare of its citizens just as it was not right for Hitler's doctors to experiment on inmates of concentration camps without their consent.

At the same time, Catholic moral teaching is not a form of libertarianism, which relies greatly on distrust of government. The Church still

cherishes the long tradition that civil authority has a duty to promote the "common good" of society. Without going into this venerable notion in detail,[7] suffice it to say here that the duty to promote the common good clearly includes some responsibility for the reasonable availability of health care in a community.

This notion would not only justify such things as government funding for medical research and education but would also support such legislation as the Uniform Anatomical Gift Act of the late 1960s, which was widely accepted and which sought to reduce legal obstacles to organ donation. Some would observe that this law did not achieve the goal of some of its designers, namely a leap in the availability of organs suitable for transplantation. Relying on voluntary action by potential donors, the law was too idealistic to achieve this goal. It is probably for this reason among others that policy makers in Delaware and other states now require that someone other than the potential donor take the responsibility for raising the issue of organ donation before the potential donor's death.[8]

Conclusion

This article has focused on one aspect of organ transplantation, namely the issue of organ donation and procurement, and it has only tried to present a moderate Catholic viewpoint on some of the ethical issues involved. While there is no complete unanimity among Catholic ethicists on these issues, most would be supportive of those who might wish to donate organs and most would not object to current laws designed to increase the availability of organs for transplantation. The fact remains, however, that especially in the area of public policy, the growing demand for organs and tissue for transplantation will continue to raise difficult questions for Catholics and for all Americans in the years to come.[9]

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CHOOSE LIFE: JEWISH TRADITION AND ORGAN TRANSPLANTATION

Kenneth S. Cohen

Deuteronomy 30:19 declares:

> I call heaven and earth to witness against you this day: I have put before you life and death, blessing and curse. Choose life--if you and your offspring would live.

Jews have traditionally emphasized the goodness, the value, the sanctity of life. Their toast at occasions of celebration has always been, *l'hayyim*, "to life." The roots of this joyous affirmation run deep into the Bible: at the end of the first chapter of Genesis, God surveys all that He has created, including humanity, and declares it to be "very good." This fundamental principle of the goodness of life, with its attendant corollaries, governs the Jewish attitude towards organ transplantation. If these medical procedures preserve and enhance life, they too are considered "very good," and deserve our serious consideration.

The goodness of life has as its supreme corollary the concept of *pikuach nefesh*, "preserving life." The rabbis indicate that with only three exceptions (murder, idolatry, and illicit sexual relations), all Biblical and rabbinic laws may be set aside to save human life. Human life is precious, a gift from God, and no one has the right to deprive himself or another of this gift, once granted. Leviticus 19:16 puts this reverence for life in the form of a commandment: "You shall not stand upon the blood of your neighbor;" ie, you may not stand idly by when a human life is threatened. We are thus bidden to intervene with all the resources at our disposal to protect and preserve existing human life.

This intervention can violate the laws of nature itself. While God did pronounce this world good, He did not declare it to be perfect. When God entrusted this creation to man's stewardship, He expressly authorized him to conquer nature and subdue it, improving it whenever necessary and possible. When we turn to such Scriptural passages as Exodus 21:19, "He shall cause him to be thoroughly healed;" Deuteronomy 4:9, "But take utmost care and watch yourselves scrupulously," or Deuteronomy 4:15, "For your own sake, therefore, be most careful," we discover the rabbis and later commentators interpreting these verses as giving Divine sanction for physicians to heal.[1] Human beings may alter nature to improve the quality of life.

The Bible estimates the sanctity and dignity of the human being and his body when it declares in Genesis 1:26,27 that humanity is created in the image of God. Jews have traditionally deemed it an act of blasphemy against God to tamper with the Divine image by submitting the body to unnecessary physical mutilation while one is alive, or by permitting mutilation of the corpse when dead. This aversion becomes pronounced when experimental surgery is contemplated, when autopsies are requested, or when body parts are to be harvested for transplantation, as will be discussed below.

Since all human life is sacred, it becomes all the

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more difficult to apportion the limited resources for healing to all those in need. Health care professionals are frequently called upon to exercise God's prerogative in determining who shall live and who shall die. While the rabbis emphasized that no person's blood is redder than another's, ie, that each person has a valid claim to life, they too, coped with the unsettling reality of triage, and offered certain speculative guidelines as to who ought to be saved first. Their judgments tend to favor those who serve the primary needs of society.[2] Nevertheless, such considerations are always reexamined on a case-by-case basis, undertaken with the greatest trepidation.

How are these basic principles applied in the case of organ transplantation? Most frequently, practical application is put forth in the *responsa*, answers proposed by noted rabbinic experts who use classic Jewish texts as the basis for their decisions. Often, these *responsa* deal with the sources for organ transplants, arguing that the manner in which these organs are obtained is decisive for the procedure's permissibility under Jewish law.

The most obvious and frequently-used source for organs is cadavers, but what constitutes a cadaver? When does Judaism regard death to have occurred? The Talmud recognizes four criteria for death: loss of movement, respiration, heartbeat, and brain function. Even in ancient times, it was understood that no single criterion alone would be a sufficient determinant of death.[3,4] Usually, the irreversible cessation of respiration and cardiac activity constituted a practical definition of death. The availability of artificial respirators, heart pumps, and more sophisticated methods of measuring brain activity have completed the definition.

For instance, today we talk about "brain death." The Harvard Criteria for the Definition of Death, issued in 1968, lists irreversible coma.[3] Secular jurists have entered the debate, as indicated by a ruling by the New York State Court of Appeals in October, 1984. The President's Commission for the Study of Ethical Problems in Medicine specified "irreversible cessation of all functions of the entire brain, including the brain stem."[4]

Rabbi Feldman observes that Jewish law requires the irreversible cessation of both higher cerebral and cortical activity, as well as the cessation of the vegetative functions of the vital centers of the brain stem, for the patient to be declared brain dead. He writes, "The heart may still be beating but, with a brain stem irreversibly gone, the patient is dead, and his functioning heart can be conceivably used as a transplant to save the life of another."[4] The heart "can conceivably be used," but not automatically or necessarily.

The earliest attempts at heart transplants created an uproar in both the scientific and religious communities, because these operations seemed to have been based on scarce experimental data. The risk-to-benefit ratio seemed skewed against the patient. It was feared the human beings were being used as guinea pigs. Today's refinements in procedure, supported by sober, careful laboratory evidence, have made heart transplant operations more viable alternatives, but there are still ethical requirements that must be satisfied to permit them. Any transplantation requires the informed, prior consent of the recipient and the donor, or by their next of kin; the timely harvesting of the organ should include two separate medical teams, donor and recipient, to obviate conflicts of interest that could in any way jeopardize the lives of the patients.

Nivul ha-met, or desecrating the human body and deriving use from its parts is usually forbidden under Jewish law. However, in his famous *responsum*, Rabbi Ezekiel Landau ordered that the suspension of any prohibition is permissible for the benefit of a patient who is *choleh lefaneinu*, "in clear and present danger."[5] While there is still some question as to whether organ banks violate this concept, fearing abuses like those depicted in the movie *Coma*, many rabbis permit them, reasoning, "there is always a shortage of donated organs and thus there is a reasonable certainty that they will be promptly used in life saving operations."[3,5]

In a landmark decision by the late Chief Rabbi of Israel, I.Y. Unterman, eye or corneal transplants were permitted because loss of sight was regarded "life threatening." Unterman addressed associated issues as well, which have been generalized towards all forms of transplantation. The prohibition against using body parts from the dead is relaxed in the belief that these transplanted organs are not, in the strictest sense, dead; they have been given new life in another's body. As long as there is a presumption that such

donations will someday be given proper burial, their use is not regarded as desecrating the human body.

What of donation of organs from non-human donors? Many have enthusiastically embraced the idea of artificial organs. If they are proved to be effective viable alternatives, they will eliminate the thorny issues involved with human organ donation. Animal organ transplantation, properly obtained, such as the use of a baboon's heart for an infant, could be considered in accordance with Jewish legal standards.[4] Animal skin grafts have been allowed. Traditional notions like *tzaar baalay hayyim*, having compassion on animals or the idea that a person is somehow de-humanized by sharing the parts of an animal, are overcome by the higher good of saving human life.

A final, and perhaps most controversial source of organ donation is from living human donors. Any operation has its accompanying risks to both the donor and recipient of a transplant. The Jerusalem Talmud requires a person to jeopardize his life to save his fellow; the Babylonian Talmud sees no such requirement, nor do the majority of subsequent authorities. Even without such legal obligation, however, "a person who donates an organ in order to save the life of another has clearly performed an act of *chesed* (lovingkindness) of the highest order."[5] As long as the possibility of saving the recipient's life is substantially greater than the risk to the donor's life or health, a fit donor may, without coercion, consent.[3,6]

This pertains especially to regenerative organs or tissues, such as blood and bone marrow, where the risk tends to be minimal,[7] but it can also be applied to non-vital, non-regenerative organs such as a kidney. Sex organ transplants, ova and testicles, while not remedying a life threatening situation, are permissible when they are performed to correct infertility, thus assisting in the fulfillment of the Biblical command to be fruitful and multiply. Paternity or maternity becomes that of the recipient.[3] While the sale of organs strikes many as morally repugnant, Jewish law permits it as due recompense for any risk or loss the donor may undergo.[7] The selling of blood has long been countenanced; it is conceivable that other organs may be sold as well. Obviously, great care must be taken to prevent abuses, lest human beings be used as organ farms, and black markets peddling human flesh arise, auctioning off life to the highest bidder.

Given its affirmative outlook on life, and its belief in life's preservation and enhancement, Judaism tends to be favorably disposed towards organ transplantation. As long as the dignity of individuals and their bodies are maintained, as long as the benefits outweigh the risks, as long as informed, voluntary consent is obtained and religious and ethical scruples are honored, Jewish tradition supports organ transplantation, for it enthusiastically chooses life.

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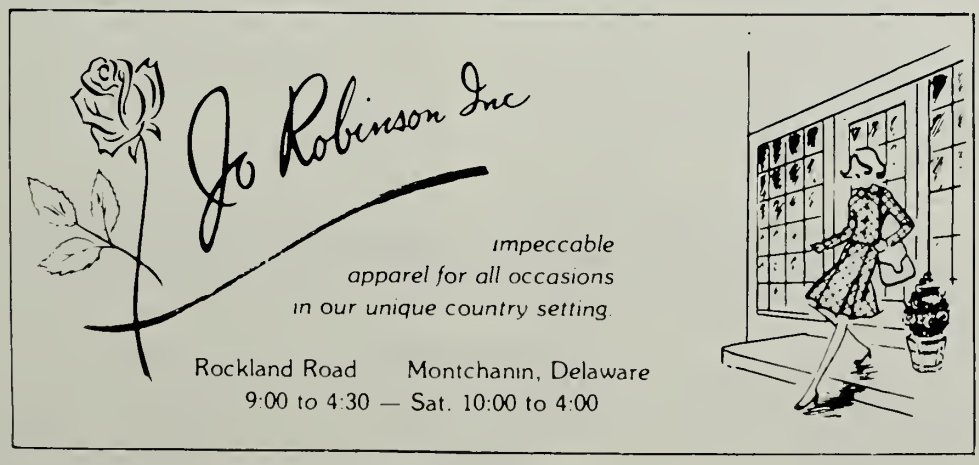

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JOHN 15:13: A PROTESTANT'S VIEW OF ORGAN DONATION

Marlene Walters, Ph.D.

What is one Protestant understanding of organ donation in our society today? If life is a gift from God, can we give parts of this gift to others? There is trust in the commonly expressed belief that life is a gift of God. However, some theologians are not content with the implication of this familiar idea and find some deficiencies. Does the giver of the gift of life require anything of the recipient? Definitely. Life is not a gift without strings attached. Christian faith emphasizes not only the autonomy and value of each one's life; but the theonomy and responsibility as well. This means that such moral imperatives as justice, love, and compassion are not virtues suddenly invented and added onto life; rather, they define what it means to be human. Life is more accurately thought of as a loan than as a gift from God. For Christian faith, human life is inescapably a moral life, depending on the physiocochemical process of the body, but far transcending it in the dimensions of the soul, spirit, and mind.

Then does the Christian belief in the resurrection of the body place any obstacles in the way of a destruction to the body through the donation of organs? Some Christians hesitate to donate their bodies because of belief in the resurrection. St. Augustine's essay, *De Sura Pro Mortius*, explains to the satisfaction of most Christians, the answer to this polemic question. At no point in this defense of burial does Augustine make the practice of burial a condition of the resurrection, as though God were somehow prevented from accomplishing His purposes with those who were smashed to pieces or incinerated. Burial, he asserts, is "no aid to salvation," but "an office of humanity." Burial is simply a fitting testimony to the resurrection; it does not condemn the body or devaluate it to the position of a disposable cartridge.[1] From this perspective, Christian faith in the resurrection does not present an insurmountable obstacle for the extraction of organs from the donor. Similarly, sharing the loan of our life is a familiar theme for Christians. Just as Jesus laid down His life for us, we are called to demonstrate this similar love for others. Even before Jesus, Hebrew ethics considered the question of the highest commandment. Jesus, faithful to that tradition, made love the supreme commandment, that includes all others within itself. Therefore, love makes no distinction between more precious and less precious, quality or non-quality of life. Every human life is a part of the human community that bestows and protects the life of its members.[2] Jesus said there is no greater love than that involved in laying down one's life for another (John 15:12, 13).

Thus, the final loan of our physical body can be given by donating organs to another person as an uncomplicated common denominator of our love and our final outreach to one another. However, as previously stated, our responsibilities for God's loan of our life are the moral and religious imperatives of justice, love, and compassion. How can we apply these imperatives to organ donation? There are several issues in need of continuous evaluation.

Organ Procurement

How should the organs be allocated? Some have advanced the theory of a free market allowing an international brokerage in cadaver organs.[3] In this market individuals are to be offered financial inducements for the donation of their organs, the price of each organ to be determined in the open market through bidding. Basically, most

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Christians would be opposed to instituting a free market such as this on the basis it might lead to injustice favoring certain elite persons in the bidding to obtain scarce organs.

It must be repeatedly stressed that it is the pride of the Judeo-Christian tradition that the weak, defenseless, powerless, unwanted, and poor are cherished and should be protected as our neighbor in greatest need. Therefore, loving and caring for all humans, regardless of their condition, are vital guidelines for the procurement of organs. These guidelines were exampled in Jesus, as the empowering disposition to serve another without thought of any good that may accrue to one's self. Fortunately, the congressional decision to enact the Organ Procurement Act of 1984 bans the sale of organs for the purpose of transplantation. However, the issues of cost, priority, definitions of death, and other incentives were not addressed.

Cost

It is not possible to put a price on life. Even if this could be done, such a practice would corrode the bonds of community that are the cement of social cohesion in every society and every religion. Equitable access of patients to organ transplantation should not be impeded by unfair financial barriers.

In the Biblical context of justice and fairness, all transplant procedures that are efficacious should be made available to all patients through a publicly funded program for patients who are without insurance, Medicare or Medicaid, and who could not otherwise afford to obtain the transplant. This should remove some of the incentives to solicit either by television appeals, prepayment plans, or underground quackeries.

Required Consent and Presumed Consent

One task force estimates that this year, 20,000 people will suffer brain death from trauma.[4] Only 15% of these people will be organ donors. When the rest are buried, they will take with them as many as 100,000 transplantable organs. The same study group proposed a solution: a required request system in which ICU staff were obligated to propose organ donation to families of brain dead patients. The program was a success, as it increased organ donors. Others have suggested a weak-required-request.[5] This option would help find donors, but recognizes the right not to donate and allows for opting out by family members. Presumed consent means that families should be asked, not for consent to the donation of organs, but whether they have any objections. Thus, informed consent is now presumed, making it relatively coercive as compared to the more classical freedom of choice that has characterized our society. In all consent situations, ethical issues need to be constantly addressed. Are the wishes of donor and family being followed? Are health care professionals making only perfunctory attempts or invoking therapeutic waivers? In order to form an ethical system of checks and balances, and adequate data collection, monitoring the rights of the donor's family is essential to assure trust and support in the community.

Since organ transplants depend on a donor, and the need for organs far exceeds the supply, education is one of the key tools for closing the gap. Recently, the Delaware Valley Transplant Program, in response to Organ Transplant Week, asked churches and synagogues to distribute brochures on one of their worship days in April or May of 1988. At my church on Sunday, April 24, 150 brochures were dispensed along with a pastor's brief message on organ donation. Ninety-two parishioners returned their organ donor cards, pledging to become organ donors. Therefore, continued education to all segments of our community can prove to be effective.

Definition of Death

One of the dilemmas in obtaining donor organs is the controversy over what constitutes death. At the turn of the century, the medical definition of death was by placing a mirror under the nose of the patient to observe signs of respiration. Not too long ago, the traditional view was the absence of heartbeat.[4] Notice these definitions were medical and not in the law books. However, in many states, including Delaware, death is now legally defined as "an irreversible cessation of function of the entire brain, including the brain stem." The primary reason for legally defining death is to assure that organs for transplantation will be available at the earliest moment and while they remain in a healthy and viable state. There are two important ethical questions constantly in need of reevaluation. First, by redefining death to ensure vital organs are available, are we subtly shifting our attitude favoring the patient as a donor of organs, rather than as a person who may

be helped medically or allowed to die peacefully? Legislation could tilt in favor of the recipient rather than the patient-donor. Secondly, will the definition of death be redefined to include other vegetative persons, who although not brain dead are in persistent vegetative states? Many ethicists, medical personnel, and legislators are debating these questions, and legislation in many states favors discontinuing treatment for those in persistent vegetative states, therefore expanding the definition of death.[6]

This opens up the question of judgment of quality of life over sanctity, usefulness over worthwhileness.[7] These new definitions of death evoke at least six questions for continuing evaluation by our entire society.

1. The moral domino or slippery slope theory: will more laws open the door to active euthanasia?

2. The Protestant theologian, Joseph Fletcher said, "The act of omission is the same as the act of commission."[8] Therefore, will it be more humane to actively euthanize the hopelessly, irreversibly ill to alleviate their suffering?

3. When is an illness in fact irreversible or hopeless?

4. Does hopelessness connote meaninglessness, thus inhibiting the use of prudentially justifiable therapy for the seriously ill?

5. Will those responsible for not feeding people in persistent vegetative states always act in the best interest of the patient, thus depriving the patient of some safeguard against human caprice?

6. Cyclosporin and other antirejection drugs are rendering more successful transplants.[9] This may mean removing organs at once eventually will not compromise the quality of these organs. Harvesting organs will be technologically possible in the near future. Should this happen, will we eliminate from our law books the definition of brain death that was written to "assure organs would be available at the earliest moment"? If we continue legally defining brain death as a flat EEG, will we then be able to legally define when life begins as a normal EEG?

These questions need ongoing deliberation and appraisement.

Conclusion

This is not an exhaustive Protestant prospective, because there are too many Protestant denominations all with varying governing policies. However, the apex of the Christian faith is the perception that the suffering that accompanies all parts of society can be overcome by the divine sharing of it. The main thrust of the cross in Christian faith appears to agree with the purpose of such applied scientific techniques as organ transplantation. Both the cross and organ donations are against the negativeness of destruction of life. However, as history has shown, even the best purposes can be corrupted. Therefore, the moral and religious imperatives of justice, love, and compassion need to be continually interfaced with the ongoing debates concerning all of medical ethics. Love is a covenant. Justice is a covenant. Both eminent, but philosophically differing Protestant theologians agree on these covenants. Those embracing the deontological theory, "What is the obligatory thing to do?"[10] and those believing in the teleological theory, "What will be the consequences?"[2] agree that transplants would benefit society. Therefore, organ donations are medically and spiritually good stewardship with justice and love as the ethical backdrop for continuous evaluation.

What were the religious imperatives of justice, love, and compassion in the Christian communities? "For the Christian community, it is the injunction of scripture to love your neighbor as your self...the sick is a neighbor...the dying is a neighbor..."[10]

The ultimate covenants incorporating justice, love, and compassion should be an ongoing dialogue with laity and professionals so that we work together in building trust and cooperation by enhancing the Great Commandment to love one another because greater love has no one than this: to give our life for our friend (John 15:13).

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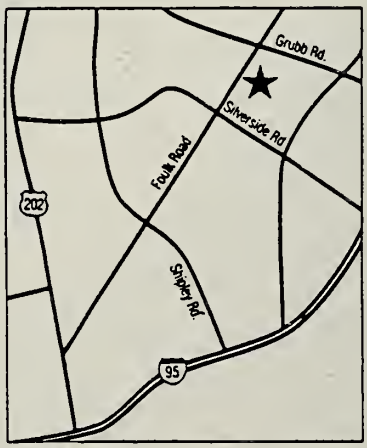

Bioethical Humor

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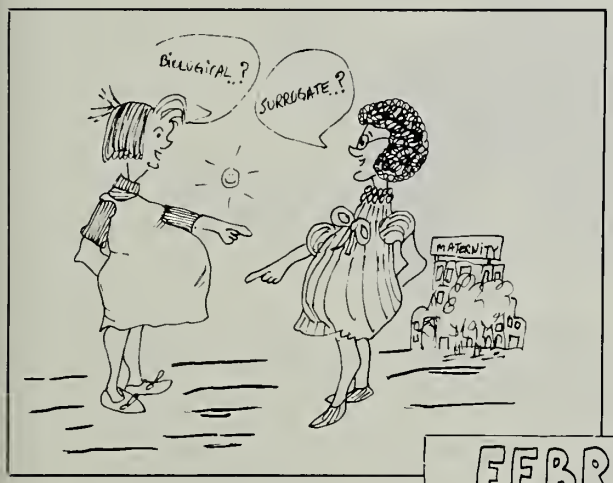

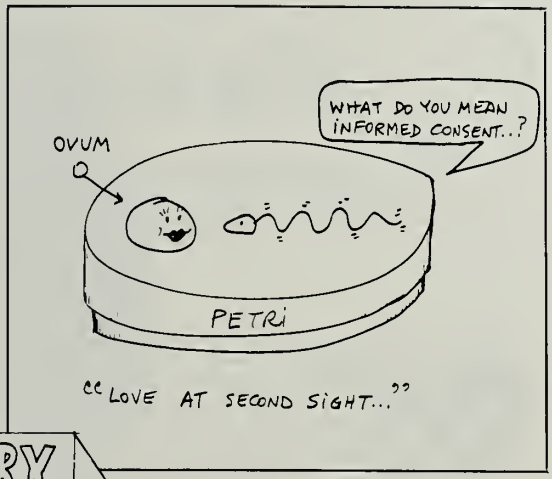

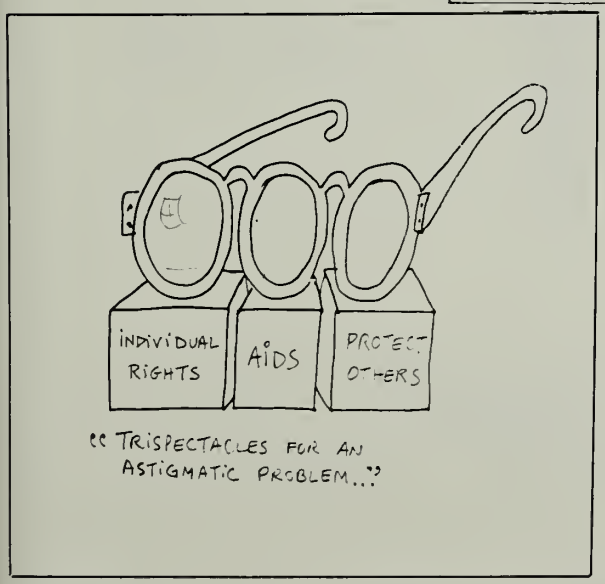

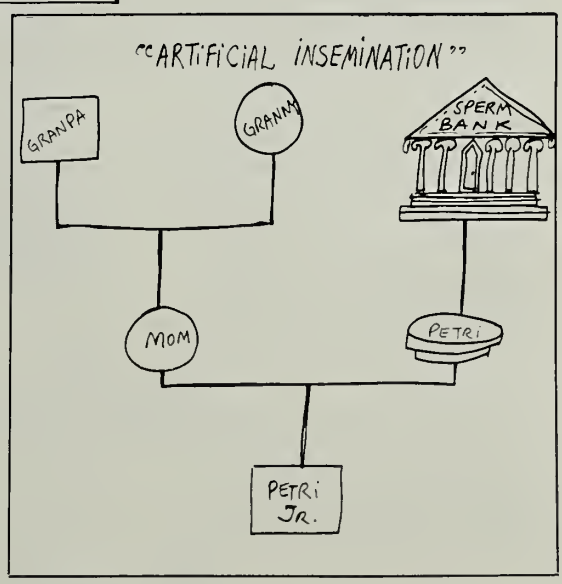

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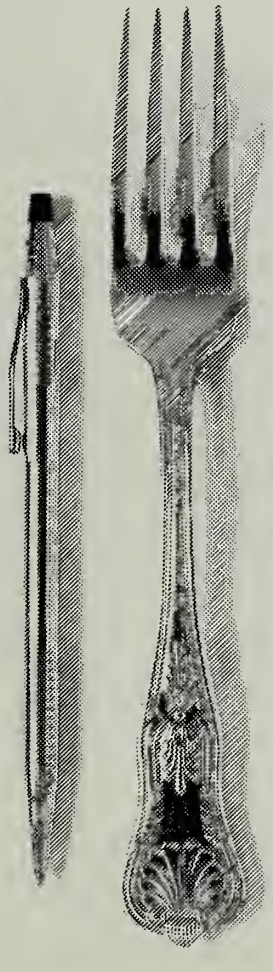

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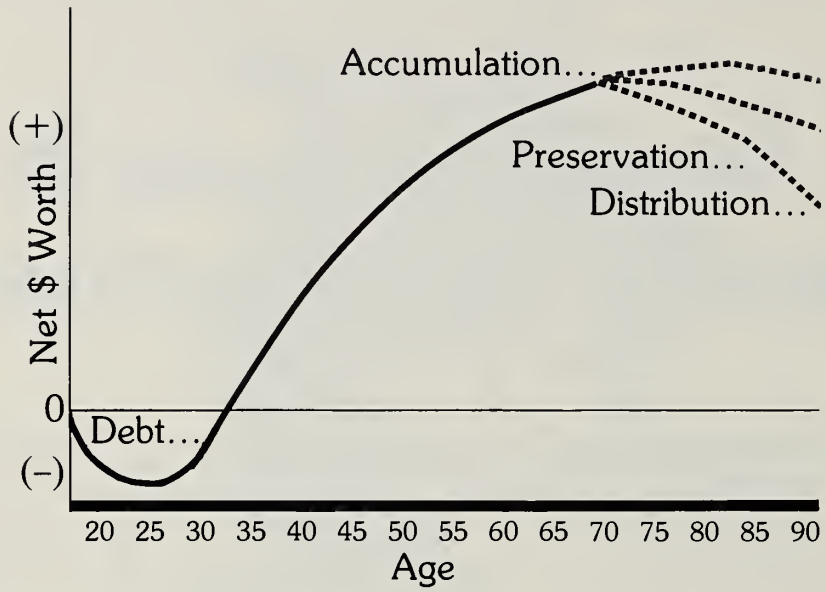

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(Continued from page 475)

temporary medicine. We physicians can no longer avoid being involved in defining "personhood" and "quality of life." As a clinician, he accepted the challenge to write about abortion in adolescents, and it is no surprise that he concluded such controversy will continue for a long time. His reflections give us stimulating food for thought.

There has been much discussion during the last few years on the role of ethics in medicine, and although everyone accepts that it is an important role, many physicians are not quite clear how to use it in daily practice. Dr. Robert Perkel of Jefferson Medical College, states in his presentation that experienced physicians need no introduction to ethical problems, since they regularly confront concrete and troublesome dilemmas in their day-to-day practice. He also explores ways to arrive from a clinical problem to an ethical decision. Dr. Perkel strongly believes that ethics should be considered a vital component of good clinical medicine.

Although we are now busy trying to find the right key to lock up the problem of AIDS, once the hysteria calms down I honestly believe that organ transplantation will be one of the most important ethical issues of the decade. Having an expert in my own backyard, I drove to the Alfred I. duPont Institute and invited Dr. John Noseworthy to write on that subject. He accepted, and in our preliminary conversation told me that in the future transplanted organs will be a therapeutic option used much more frequently. The ethical dilemmas he discusses in his paper are how to obtain organs (selection of donors); who should receive the organs (selection of recipients); and how will society make financial resources available (who will pay the bill)?

A side effect of the discussion on organ transplantation is the vicarious stimulation of our sensitive religious nerves. It is apparent that our Judeo-Christian heritage either influences our thought more than we are willing to accept, or I am getting old... To be at peace with my conscience, I asked three religious leaders for their opinion on this matter. Their answers were surprisingly candid, and they arrived at very similar, very practical, and common sense conclusions. I truly enjoyed reading them and in the end, I had the satisfying feeling of knowing there is hope for ecumenical consensus.

To encourage and reward that senior physician who feels ready to rediscover with me the very intimate emotion we felt when we first received our medical diploma, I will conclude this introduction with the masterful words of Confucius:

> If a man keeps cherishing his old knowledge, so as continually to be acquiring new, he may be a teacher of others...

Maurice Liebesman, M.D.

INFORMED CONSENT: AN ETHICS QUESTION?

Patients who join clinical research trials have the right to be well informed about the protocols they are entering. Their studies have been carefully designed and peer reviewed with an appropriate informed consent requirement. Those hospitals where most patients enter research protocols are required by federal legislation to have Institutional Review Boards (IRB), a requirement based on ethical and legal precepts that a patient involved in a research study should be fully informed about the study. Research studies are not

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only initiated by prestigious university centers and have the approval of such bodies as the National Cancer Institute, but also need local approval by a properly conducted and approved IRB.

Informed consent documents designed for patient use, with a series of required items, have become more complicated and much longer in the past three to six years. No longer is it proper to have a blanket consent form. Each study requires specific information in the informed consent document and needs approval from Washington. The local IRB is allowed to add items to the informed consent and to question the research protocol, but its role is largely concerned with whether local patients will understand the research study from the consent form. In spite of the increasing complexity of the consent process, a significant number of physicians and patients continue to participate in clinical research studies. (Twenty to 30 years ago, verbal consent was considered enough before trying a new drug or procedure.) Current IRB and informed consent barriers obviously inhibit research participation, but public and professional ethical considerations give priority to patients' rights to know. As a result, progress is slowed in the clinical application of many new approaches to diagnosis and treatment.

For example, only an estimated 3% of breast cancer patients eligible for adjuvant trials nationally are participating, and in Delaware, there is a 6-10% participation rate. While there is now a 5-10% improvement in survival secondary to adjuvant therapy, the ten year survivorship is far from a 90+% rate, which should eventually be possible. In other words, too many women are still dying of breast cancer. We cannot be satisfied with today's advances although they are significant. (As an aside, there appears to be no adverse malpractice experience with patients on research studies.)

Many articles have been written, frequently by non-clinicians about the ethics of recruiting patients for research studies.[1,2] There is concern that patients may be urged to participate even though the responsible physician is convinced that one arm of a randomized study is superior. Such apparent conflicts of interest suggest that physician investigators may have ethical dilemmas. Most clinical investigators who have a

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strong bias for one arm versus another will not participate. However, they frequently recognize that their personal prejudices may have no scientific basis and that clinical impressions are often wrong. If there is significant evidence which appears to favor one procedure over another, most investigators will not suggest that a patient enter a given study. Research studies nevertheless are usually designed scrupulously, with evenly balanced regimes, for specific classes of patients, so that there truly is no choice. Any arm of a study could prove to be the best. Only a clinical trial can make the determination.

Clinical research studies are divided into three phases. Phase I consists of tests to determine toxicity and acceptable doses of new drugs after preliminary animal tests suggest they may be of value. The patient candidates usually have end-stage disease for which customary therapy has been exhausted. Phase II studies will use the doses defined by the Phase I studies to determine if they have an effect for specific disease. Phase II patients usually have advanced disease for which there is no other reasonable treatment. Phase III compares a "standard" therapy to the new drug shown to be effective in a Phase II study, to determine whether the new treatment is any better than the "standard," which in some cases may mean no treatment at all. In this way, through the clinical application of basic research, improved standards of therapy develop. Community hospitals are usually only involved in Phase III, and in a few Phase II studies.

Now to raise the big ethical question for Delaware: is it ethical to deprive a Delaware patient of an opportunity to participate in a research study which offers the possibility of an improvement or even a cure? Shouldn't a patient eligible for a research protocol be allowed to sign either a consent or a refusal form? Aren't physicians obligated ethically to inform their patients of all treatment options, including those for whom a 90+% response rate and survival benefit can be anticipated, or for extenuating circumstances (usually psychological)? Why not offer all eligible patients research studies approved by a hospital's IRB? How can physicians on a hospital staff ethically not inform patients of their options? Why shouldn't patients with similar diseases be given as much information as those involved in research protocols? Second opinions are required by many third party insurers, and in some states the full disclosure of a patient's options for breast cancer treatment is required by law. Since this preoperative concept has been accepted, frequently reluctantly, by the medical profession, shouldn't medically promoted consent forms also be routine for eligible patients? Acceptance of this practice should mean better informed patients, better quality of care approaching the state-of-the-art protocol requirements, increased participation in high priority Phase II studies, and probably fewer malpractice suits and the associated premium increases.

This proposition should enhance medical care both directly and indirectly, and therefore, by following the ethical standards set by the research community professionally establish new standards of care not necessarily related to the bottom line of finance, which all too often appears to be the goal.

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AIDS HYSTERIA IN DELAWARE

The recently postponed decision of the Nemours Foundation to refuse employment to HIV positive applicants and to remove from patient care areas any employees found to be HIV positive was and still is ethically insupportable. HIV infection is not transmitted by casual contact. It is transmitted by sexual intercourse, by sharing of IV drug needles, and from mothers to their children at the time of birth. There is no scientific basis for the position taken by Alfred I. duPont Institute. HIV infection is a sexually transmitted disease, and it must be dealt with according to established principles of public health, not with hysterical responses that are not grounded in scientific reality.

The Institute's position on HIV positive employees implied that HIV is transmissible by casual contact. This implication is damaging to Delaware's effort to prevent persecution of HIV positive individuals. If people are afraid of losing their jobs, of being thrown out of school or denied housing, they will be less likely to volunteer to be tested. Voluntary testing is a key element of our state's fight against the AIDS epidemic. When a large institution announces that it will deny employment to an HIV positive individual, it reinforces the fears of persecution which are keeping large segments of the population away from HIV testing.

The fact that the institution announcing this policy is a hospital, a medical institution, makes the effect of the action even more devastating. The general public will interpret the hospital's decision as an indication that *doctors* believe that the disease *can be* transmitted by casual contact. This misconception will cause more blatant discrimination against HIV positive individuals and that in turn will keep people from volunteering to be tested.

An infected individual who is not diagnosed as HIV positive because of fears of persecution, is denying himself medication which could prolong his disease-free period. He is denying his doctors information which could increase their index of suspicion of unusual diseases to which immune deficient individuals are subject. He may also continue to place at risk loved ones who may not yet have been infected. A woman may make decisions about her reproductive life that she would have made differently if she had known that she was HIV positive.

A similarly inappropriate approach to the issue of AIDS is Representative Oberle's recent unsuccessful attempt to make it possible to put a physician in jail if the physician was found guilty of ordering an HIV test without having first jumped through a number of complex hoops, including providing the patient with:

1. An explanation of the test, including its purpose, potential uses, limitations, and the meaning of its results;
2. An explanation of the procedure to be followed, including that the test is voluntary, that the consent may be withdrawn;
3. An explanation of the nature of AIDS and other manifestations of HIV infection and the relationship between the test results and those diseases.

With the threat of a jail term hanging over his head, it is conceivable that many a physician would worry that he might not be able to explain "the nature of AIDS" to the satisfaction of a court of law. This, like Alfred I. duPont Institute's controversial position, would decrease the number of HIV tests performed, and would delay timely di-

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agnosis and treatment of the HIV positive individual.

Criminal sanctions should be taken against those individuals and institutions who intentionally discriminate against HIV positive persons, whether in the area of employment, housing, or education, not against physicians who attempt to diagnose the disease.

The public health problems posed by this disease must be dealt with according to established principles of the disciplines of public health and infectious disease. Approached in that manner, the problems can be solved. This is a preventable epidemic. The United States has the resources needed to muster an educational effort that could stop the spread of AIDS. The Institute's actions were counterproductive to that educational effort. It is the responsibility of physicians to speak out against AIDS hysteria, and to insist that public policy reflect scientific fact.

Diana Dickson-Witmer, M.D.

CARE OF THE BRAIN DEAD AND OTHER TROUBLING PATIENTS

"Determination of death: An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions; or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards."

This definition has been effective in Delaware since 1986. It seems so settled now. However, extensive discussion was started 18 years earlier with the publication in 1968 of "A Definition of Irreversible Coma,"[1] and continued for at least 13 years until the report of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.[2] A further five years was still necessary before such a definition was accepted in Delaware.

During these years, it was noted that the out-

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come was uniformly fatal for these patients (exception young children) and that termination occurred usually within a few days or rarely weeks. This outcome occurred even with continued and determined maximal support. The final acknowledgment that such an irreversible state existed helped to alleviate the discouragement that often pervaded the staff of the units caring for these patients, and also some of the anger and resentment of family members.

The delineation of the proper course in the care of patients who are brain dead is now determined by the medical findings and the conclusions that are drawn from them.

But what of the care of those who are not brain dead? What of the patients who are in:

a persistent vegetative state;

a permanently altered state of consciousness but not vegetative;

a terminally ill and incompetent state;

a terminally ill and competent state;

a seriously but not terminal ill and incompetent state; and

a seriously but not terminal ill and competent state?

The competent patient's rights to privacy and autonomy, ie, the right to deny consent to treatment, have usually been sustained in the courts where these have been questioned. But what if no direction is available from the patient, and no advance directive has been set down? How many of our patients have completed a will and testament proper to illness or entering a hospital? Certainly even fewer patients have thought of executing a living will or durable power of attorney.

I hope that whenever a will and testament is being considered that the lawyer involved will also counsel about the availability of a living will and durable power of attorney, and that ministers of the various religions will discuss the obligation that the individual has to give directions as to his/her care in times of illness, and that physicians (particularly primary care physicians) will initiate similar discussions as part of their routine review of their patients' health status.

Unfortunately, there will still be many situations in which a patient will be unable to participate in treatment decisions due to illness. Usually the family or next of kin has been relied upon in those situations to supply a substantiated judgment for the patient. But increasingly, particularly in decisions involving withdrawal of care from patients, the courts have mandated other arrangements for these decisions. This has caused increased uncertainty and confusion among those who care for these patients.

My suggestion is that the judiciary and legislature now cooperate to give clear instructions as to a timely and reasonable method to apply to these difficult situations.

Thomas S. Vates, Jr., M.D.

References

1. Report of the Ad Hoc Committee of Harvard Medical School to Examine the Definition of Brain Death. A definition of irreversible coma. JAMA. 1968; 205:337-340.

2. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. Defining death: medical, legal, and ethical issues in determination of death. Washington, DC: US Government Printing Office; 1981.

QUANDARIES IN REPRODUCTIVE TECHNOLOGY

Carl Sandberg said it best: "Babies are God's word that the world should go on." When couples are faced with the horror of infertility, it can have a profound effect on their marriage and on each partner individually. Adoption has become a preciously scarce option. Traditional evaluation and

treatment for reproductive failure was successful for approximately 50-60% of families. In 1977, with the birth of Baby Louise Brown in England, the age of assisted reproductive technology has launched into an exciting new era of hope for couples who previously had exhausted their options. With the birth of this new technology, many ethical, religious, and financial dilemmas have been raised.

The Wall Street Journal highlighted our current quandary when it posed the interesting scenario that could be faced by a child born as the product of scientific advancement and change in societal thinking. A donated ovum is fertilized from the donor sperm. The zygote is then implanted into a surrogate mother. The newborn is adopted by an infertile couple. The child would, in fact, have five parents. The highly publicized Whitehead surrogate parenting case is another sobering reminder of the challenge that society faces when dealing with the new technological success.

Formal legislation dealing with such a complex and emotionally charged issue would be ill-advised. The fate of couples devastated by infertility should be dealt with privately by the couple and their physician within the bounds of their personal, ethical, and religious beliefs; not in courts of law, and not in the halls of Congress. Societal input should come from Institutional Ethics Committees served by physicians, nurses, attorneys, basic scientists, ethicists, theologians, administrators, and couples who are infertile and have conquered infertility. A required primer for such a committee would be *Ethical Considerations of the New Reproductive Technologies.* This superb work is an extremely balanced, informative, and very clearly written treatise by a distinguished panel with a broad background. Institutional ethics committees can interpret and tailor guidelines to meet the needs of the communities they serve.

Financial concerns are not an insignificant consideration in being able to take advantage of the new therapies. Cost containment in medicine is a top priority in government, industry, with third party insurers, and the general public. Consumer

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priorities have become an important issue as to how the insurance dollar is spent. A valid querulousness has been expressed with the decision to spend insurance health care dollars to treat the ravages of those who choose to smoke, consume excessive alcohol, overeat, treat accident-acquired injuries that could have been prevented if seatbelts had been worn in car accidents, or helmets had been worn by motorcyclists.

A courageous alignment of previously and currently infertile couples with the support of many in the medical and legislative community are waging an inspirational battle to bring about legislation in Delaware similar to that in place in other states to support insurance coverage for in vitro fertilization. The three year battle has successfully achieved passage of a bill in the House of Representatives, and this year the bill will move to the Senate in Dover for their consideration. This legislation deserves the vigorous support of our entire community.

Hazlitt once said, "Man is the only animal that both laughs and weeps because he is the only animal struck with the difference between what things are and what things ought to be." So it is with infertility. With the new technology, there is hope for couples fighting to escape the nightmare of barrenness. There are also wrenching new ethical and financial issues that need to be dealt with thoughtfully, compassionately, and expeditiously because time inexorably passes for the infertile couples who are waiting.

Jeffry I. Komins, M.D.

MEDICAL NEED AND THE PRIVATE PRACTICE PHYSICIAN

In this affluent country of ours, there is still a vast quantity of medical need. Thirty-seven million Americans have no health insurance of any kind; all savings they have will be wiped out by any prolonged illness. Millions of other Americans have incomes far below the poverty level, and contrary to popular belief, they are not all covered by Medicaid. To have such coverage, one must not only be indigent, but fit neatly into one

of five categories (elderly, blind, disabled, dependent child, family of dependent child). Others fall between the cracks and get no help. Then every year there are millions more who thought they had adequate coverage, but find that long term nursing home care is not covered; they are impoverished by the $22,000 per year bill.

All this represents an ethical problem for the practicing physician. Formerly, before the advent of all the government programs, privately practicing physicians recognized the problem and faced up to it. They continued to see less fortunate patients in their offices for part pay or no pay, as the need arose. And they served in hospital clinics without pay.

Now this is no longer adequate. With the growth of medical science, diagnosis and treatment can be expensive. And it would be wrong ethically to deny some of our patients the benefits of the new technology just because they are poor or cannot afford private insurance.

The tendency is for physicians to say, "The government will take care of it." But to be really ethical, to be true to our oaths, physicians must continue to look after the interests of the poor. They must continue to do what they can personally in office and clinic; and, in addition, through their organized medical societies they must monitor closely what the government is doing and demand that funds be assigned to provide good care for the poor, regardless of rigid categories. Where this is insufficient, medical societies must organize physicians to devise and operate voluntary programs to provide medical care for the needy.

Medical want must not be allowed to go on in our midst.

David Platt, M.D.

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SAVING OUR OZONE LAYER: THE DUPONT COMPANY'S DECISION

This is the second issue of the *Delaware Medical Journal* to focus on medical ethics. Both these special issues have been produced by guest editor Dr. Maurice Liebesman.

Important concerns about contemporary ethics are not, however, unique to medical practice. In the recent past many of our large corporations have been accused, chided, or convicted of unethical practices. It was, therefore, doubly pleasant to have the moralistic and usually highly critical *New York Times* laud the recent decision of the DuPont Company to phase out the manufacture of ozone-damaging chlorofluorocarbons. Cynthia Pollock Shea, a senior researcher at the Worldwatch Institute in Washington, described DuPont's decision as an "act that breaks new ground...and shows that corporate America can take steps to protect the global environment."[1]

About 15 years ago atmospheric/stratospheric scientists came up with a new and worrisome theory: our ozone layer, protection against harmful solar rays, is leaking away through a hole, and chlorofluorocarbons (CFCs) are in part responsible. DuPont was doubtful of the theory at that time but pledged that if CFCs were ever found to be a "threat to public health," it would cease their manufacture.

In 1978, these compounds were banned in aerosols because of concern over ozone depletion. This year, the leaking hole over Antarctica was confirmed and a similar but smaller hole found over the Arctic. Among the untoward results of a thinned ozone layer and holes in it, are increased solar irradiation of the earth and its

mammals, including those sun-sensitive mammals, men and women. Without the cessation of further liberation into the atmosphere of CFCs, it is estimated (in the type of extrapolation which excellent scientists seem to permit) that "10 million to 15 million Americans born before 2075 would otherwise develop skin cancer and 2 to 3 million would develop cataracts from the loss of the ozone shield caused by the fluorocarbons."[1]

DuPont might have continued its CFC manufacture, at least for some years, while fighting the accuracy and importance of the ozone leaks, much as the tobacco industry keeps denying the link of cigarettes to cancer. But when the data described began to show a more rapid depletion of the ozone layer, they honored their pledge, and the Company began to phase out its $600 million industry.

As physicians, and inhabitants of planet Earth, we congratulate DuPont on this ethical commercial action.

Good industries make good neighbors.

Bernadine Z. Paulshock, M.D.

Reference

1. Shea CP. Why DuPont gave up $600 million. NY Times. April 10, 1988, F-2.

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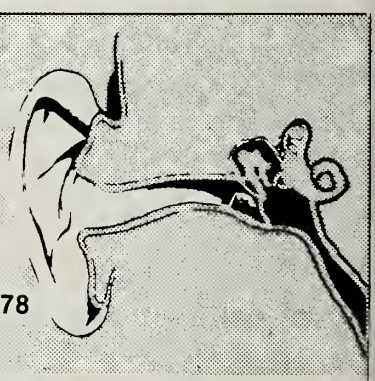

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DEATHS

PHILIP REED WALKER, M.D.

Dr. Philip Reed Walker, a former director of anesthesiology at St. Francis Hospital in Wilmington, died July 19, 1988, of complications from a stroke. He was 56.

Dr. Walker graduated from the University of Alberta in Edmonton, Alberta, Canada, in 1958. He joined the staff at St. Francis Hospital in 1967, retiring in 1984. Dr. Walker was a member of the New Castle County Medical Society, the Medical Society of Delaware, the American Medical Association, and the American Society of Anesthesiologists.

GEORGE J. BOINES, M.D.

Dr. George J. Boines, a family practitioner who practiced in the Wilmington area for more than 45 years, died July 8, 1988, of heart failure. He was 87.

Dr. Boines was born in Sparta, Greece, and came to the United States as a child. He graduated from the University of Delaware and took his medical degree at Jefferson Medical School in 1929. Dr. Boines is believed to be the first Delawarean of Greek descent to become a medical doctor.

Although Dr. Boines was a family practitioner, in later years he concentrated his practice on the treatment of polio and multiple sclerosis. He retired in 1975.

Dr. Boines was a member of the American Medical Association, the Medical Society of Delaware, and the New Castle County Medical Society.

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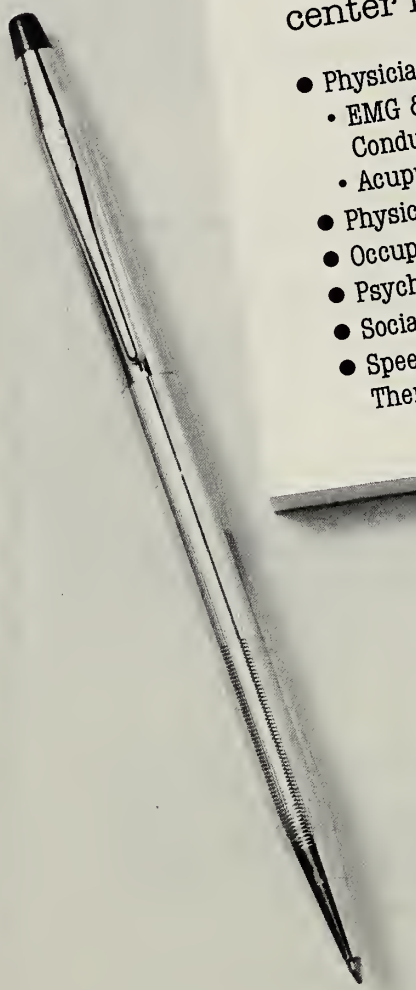

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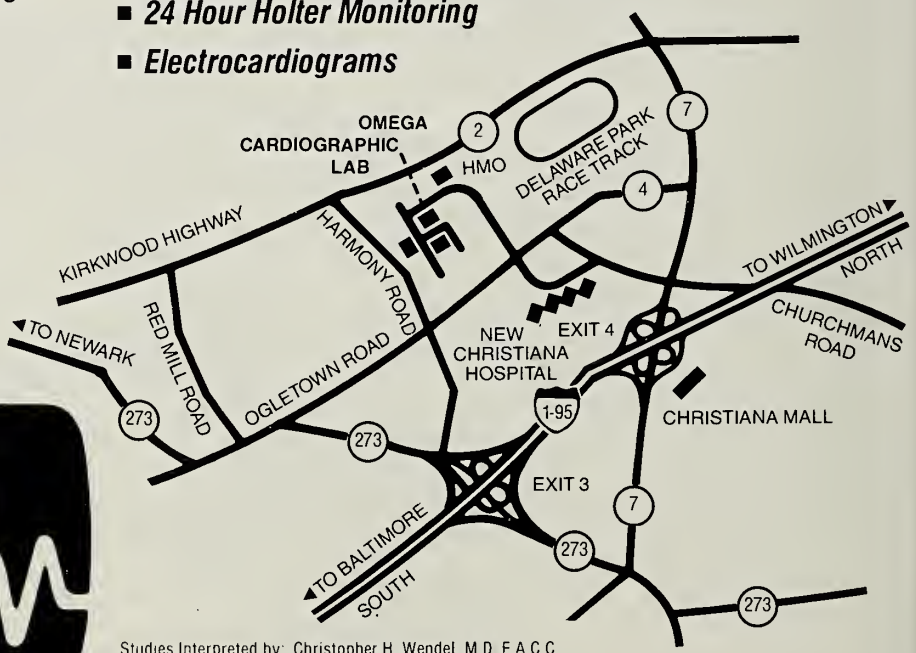

Studies Interpreted by: Christopher H. Wendel, M.D. F.A.C.C.,
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In Brief

PHYSICIAN'S HEALTH COMMITTEE

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COLLEAGUES IN THE NEWS

Bikash Bose, M.D., and several colleagues have published a paper entitled "Evolving Focal Cerebral Ischemia in Cats: Spatial Correlation of Nuclear Magnetic Resonance Imaging, Cerebral Blood Flow, Tetrazolium Staining, and Histopathology," which appeared in the January, 1988 isssue of *Stroke.*

Dean L. Winslow, M.D., a major in the 159th TAC Clinic, Louisiana Air National Guard, was recently awarded the Malcolm C. Grow Award on the Air National Guard level. The award was established in 1961 to further the aim of the Society of United States Air Force Flight Surgeons, which is to advance the practice of aerospace medicine. The Malcom C. Grow awardee then represents the Air National Guard in an all-military competition. The winner will receive the Air Force Award.

Robert D. Hunt, M.D. has passed the certification examination of the American Medical Society on Alcoholism and Other Drug Dependencies (AMSAODD) and is recognized by that Society as knowledgeable and expert in chemical dependence.

CLINICAL MEETING AND NOTICES

PSYCHOSOCIAL ISSUES FOR FAMILY PHYSICIANS

Saturday, October 22, 1988 at the Quality Inn, College Conference Center in Westminster, Maryland. The program is accredited for 6.25 hours of Category I credit. For more information, contact the Maryland Academy of Family Physicians, 5700 Executive Drive, Suite 110, Baltimore, Maryland, 21228.

AMERICAN CANCER SOCIETY NATIONAL CONFERENCE

The American Cancer Society will hold a National Conference on Advances in Cancer Management December 7-9, 1988 at the Hyatt Regency Hotel in Los Angeles, California. The objective of the conference is to increase health professionals' knowledge about advances in cancer management. The conference is accredited for 16 hours of Category I credit. For more information, write to the American Cancer Society, National Conference on Advances in Cancer Management, 3340 Peachtree Road, NE, Atlanta, Georgia, 30026.

AESTHETIC OCULOPLASTIC SURGERY CONFERENCE

The Division of Plastic and Reconstructive Surgery at Manhattan Eye, Ear and Throat Hospital is holding a seminar on aesthetic oculoplastic surgery November 3-5, 1988 at the Waldorf Astoria Hotel in New York. Live, televised surgery will supplement lectures and panel discussions. The course is accredited for 17 hours of Category I credit. Registration ends on October 13, 1988. For more information contact Francine Leinhardt, Course Coordinator, Manhatten Eye, Ear and Throat Hospital, 210 East 64th Street, New York, New York, 10021, or call 212-838-9200, ext. 2776.

FIFTH ANNUAL MENTAL ILLNESS WEEK

The theme for the Fifth Annual Mental Illness Week, October 2-8, 1988 will be "Let's Talk About Mental Illness." The Psychiatric Society of Delaware will join national groups to talk about mental illness. Materials have been developed for public distribution. For more information contact the Psychiatric Society of Delaware, Suite B-10, Trolley Square, Wilmington, Delaware 19806 or call 654-6353.

PRIMARY CARE UPDATE

The 73rd Scientific Assembly of Interstate Postgraduate Medical Association of North America will be held October 31 through November 3, 1988, at Bally's Hotel in Reno, Nevada. Key topics will include cardiology, geriatrics, endocrinology, gynecology, orthopedics, breast cancer, pediatrics, and gastroenterology. Practical office management for the primary care physician will be emphasized. The program is accredited for 24 hours of Category I credit. For more information, contact H.B. Maroney, Executive Director, Interstate Postgraduate Medical Association of North America, PO Box 1109, Madison, Wisconsin, or call 608-257-6781.

AMA NATIONAL POLITICAL EDUCATION CONFERENCE

The AMA is offering a program on October 4-5, 1988 at the Sheraton Washington Hotel in Washington, D.C. It is the only f ederally focused AMA educational/informational program offering the opportunity for one-on-one federal political contacts. Capitol Hill legislative visits will be included in the conference. For more information, contact the AMA Department of Political Education, 1101 Vermont Avenue, NW Washington, D.C., 20005, or call 202-789-7400.

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AMERICAN COLLEGE OF CHEST PHYSICIANS

The 54th Annual Scientific Assembly of the American College of Chest Physicians will be held October 3-7, 1988 in Anaheim, California. Featured will be a series of sessions on new and high technology in cardiopulmonary medicine and surgery. For more information contact the American College of Chest Physicians, 911 Busse Highway, Park Ridge, Illinois, 60068-2375, or call 312-698-2200.

SOUTH CAROLINA ACADEMY OF FAMILY PHYSICIANS

The 40th Annual Scientific Assembly of the South Carolina Academy of Family Physicians will be held at the Inter-Continental Hotel on Hilton Head Island, South Carolina. The program is accredited for 19.25 hours of Category I credit. For more information, contact Mrs. Margaret A. Turner, Executive Director, South Carolina Academy of Family Physicians, PO Box 771, Mauldin, South Carolina, 29662, or call 803-288-6647.

199th ANNUAL MEETING OF MEDICAL SOCIETY OF DELAWARE

The 199th Annual Meeting of the Medical Society of Delaware will be held November 18 and 19, 1988. On Friday, November 18 at the Delaware Academy of Medicine Bulding in Wilmington, Reference Committees will meet at 10:00 a.m., and the House of Delegates will convene at 1:30 p.m. The Scientific Session will be held on Saturday, November 19 at the Hotel duPont in Wilmington starting at 8:30 a.m. For more information, call the Medical Society of Delaware at 658-7596 or downstate at 800-348-6800.

ACEP ANNUAL MEETING

The Annual Meeting of the Delaware Chapter of the American College of Emergency Physicians will be held November 18, 1988 in Wilmington. Although plans are incomplete at this time, the Annual Meeting will be held in conjunction with the Medical Society of Delaware's Annual Meeting. For more details, please call Mark Plaster, M.D., president of ACEP at 421-4335.

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DELAWARE
MEDICAL JOURNAL

JOHN A. BROWN, BOTANIC PHYSICIAN

Everett D. Bryan, M.D.

Dr. John A. Brown

I am an amateur historian with a special interest in Delaware mercantile history. About 20 years ago, I decided to collect something related to Delaware businesses, namely any type of early bottle marked with the name of a Delaware town or a Delaware business. My collection of 700 bottles has been dontated to the Delaware Division of Museums. In 1979, a friend who was then a historian for the Delaware Bureau of Archaeology and Historic Preservation was gathering material on a historic Wilmington house called The Anchorage, for nomination to the National Register of Historic Places. One of the house's owners had been Dr. John A. Brown. My friend had seen an ad in an early newspaper for Dr. Brown's medicinal root beer, and thought I might know who Dr. Brown was, and that I might have one of his bottles, but I had never heard of him. His question, however, prompted me to find out about Dr. Brown, and I discovered him to be a very interesting person indeed.

* * *

John Agustus Brown was born in Westminster, Massachusetts, in the spring of 1810. His father died soon afterward, and at age seven he, his brother, mother, and step-father moved to Ashby, Massachusetts. When John was 17, he left home to work as a carpenter's apprentice. After about one year of this, he, as he put it in his autobiography,[1]

> ...injured my stomach by over exerting, which occasioned internal bleeding to a considerable extent, and reduced me to such a feeble state of health that, for the two succeeding years, I was unable to follow any laborous occupation whatsoever.
>
> I was destitute of any means of support, but what the kind charity of my friends bestowed upon me, and for which, thank God, they ever have had, and I trust, will ever, have, my heart felt gratitude. I ever bore it in mind, however, that he who will not endeavor

Dr. Bryan is a family practitioner in Dover. This article was adapted from a talk given by him to the History Section of the College of Physicians of Philadelphia in 1985.

to help himself is unworthy of the aid of others. In conformity with this maxim, I employed myself during the summer months, mostly spent in Boston, in some light occupation, and in the winter devoted myself to teaching school....

At the age of 20 I commenced a new mode of life--I engaged in a sort of trading enterprise, purchasing country produce and disposing of it in the market. This business I followed during the warm weather for four years...and found my health much improved. A considerable portion of my time, during my attendance at school, and most of the last term, was employed in the reading and study of medical works. For this, a good opportunity was afforded me, as I happened to room with a medical student, who was very anxious that I should also take up the study, for which I had a strong inclination. Had I not found so many contradictions in the theory and practice of medicine, I might have studied the profession, and now be a dealer in *mineral drugs*, with a mind so prejudiced against every thing out of the *regular* path of medical science as to prevent me even from examining the pretensions of any other system.

Dr. Brown noted that in addition to his lack of funds, what he called the "manifest absurdities" of the medical schools' teachings kept him from a regular medical career. I wish he had listed his exact objections so we could study them. What began him in his eventual career, he says, was hearing during his earliest days in Boston, of people who were "snatched from the very jaws of death, and rescued from the yawning chasm of the tomb, by the almost miraculous powers of the health restoring system of Thomson." Here, he first mentions the name of the man of whose medical system he would soon become a disciple.

The year following that in which I removed to Boston, the small pox made its appearance in that city. I had not had the small pox, nor had I been vaccinated. Accordingly I applied to a respectable *regular* physician--one so called, at least, and was vaccinated with, as he said, pure and fresh vaccine or kine pox matter; and for which I paid him, if my recollection serves me, three dollars, as his fee for the operation.

In due time, the innoculation appeared to have taken effect; a pustule was formed, and filled; and after the usual process, disappeared. But later circumstances have satisfied me that the matter used by the physician was far from being pure. Soon after this event, I found myself affected with bad and troublesome humors, which, from the time of their first appearance, continued to grow worse and worse. At length they became so bad that I was compelled to relinquish my business in Boston and return to the country in order, if possible, to regain my health. I then visited one of my relatives who kept the Thomsonian medicine, and who used it in his family.

A great many people will take a thing at the hand of a friend which they would not dare to purchase. So it was with me. I begged the "Composition Powder" from my relative and took it, and the effect was very salutary. However, instead of taking more, I applied to an old Indian doctress, who gave me some vegetable medicine from which, though I did not receive immediate relief, I think I finally experienced a good effect. After this, I returned to the country where, in the course of a few weeks, my health was so far improved as to enable me to resume my business in Boston. But I feel the effects of the *poisonous virus* with which I was vaccinated even to the present day.

About six months later I visted home, and my brother fell ill the day after my arrival, being slightly attacked with a bowel complaint. The family, easily alarmed, proposed to send for a doctor. My own experience had somewhat prejudiced me against the poison craft, and I made some slight objection to doing so; however, a messenger was dispatched and a doctor called. At length he came--and mark the result! The physician entered the house with that air of consequence and importance peculiar to the learned faculty. As usual he commenced dealing out his medicine, the daily effects of which are sufficient to satisfy any one not blinded by the show and glitter of assumed greatness, of its deadly properties and fatal result. Each dose of the vile drug aggravated, instead of alleviating, the complaint, and enhanced, instead of ameloriating, the torture of the suffering victim. The visits of the doctor con-

tinued for a week, when exhausted nature gave up the struggle, and the hand of death relieved the patient from his cruel sufferings. During this trying scene I had somehow obtained the impression that his complaint might have been cured by means of the Botanic Practice. And that impression was strengthened and confirmed by other cases.

On the day previous to the decease of my brother, my father-in-law was taken sick. Being exhausted by the fatigues of night watching, by loss of sleep, and anxiety of mind, he laid down to take some rest, and on awakening, found himself severely attacked with racking pain throughout his whole system. This was followed by cholera morbus similar to that under which my brother was then suffering. Had I not fortunately been at home, no doubt the doctor would have had another job, and death might have numbered another victim. As it was, his feet were bathed, and he was deposited in bed. I then undertook to produce perspiration, by placing hot stones at his feet and adding extra covering to his bed. It was my first essay in the healing art, and though I now see it was rather a bungling one, yet I succeeded, and that was sufficient. My object in attempting to excite perspiration was to remove the chills and the lameness, and while those measures were going on, I had caused brandy and sage tea to be provided, the only medicines with which I was much acquainted. I then commenced giving the brandy to *my* patient--my *first* one--in doses of a wine glass full at a time, sweetened with loaf sugar, as often as there were returns of pain; and to keep up the perspiration, the sage tea was copiously administered, and the stones at his feet kept hot. By persevering in this course he was kept free from pain and the looseness of the bowels was checked. During the night he had swallowed about a pint and a half of brandy, and several quarts of the tea, and in the morning he was free from the complaint. That morning my sister, age 15, was violently attacked by the same illness, and by my administrations, was restored to health before night.

These cases brought the subject of the medical practice home to my own bosom, and they fixed deep and solemn impressions on my mind, which can never be erased as long as life remains and reason holds her seat. From this time I went forward with the determination to look into the Thomsonian System, and to know all I could learn of the botanic practice, for I had become fully satisfied that there was neither certainty nor safety in the regular system. I formed this resolution without the remotest idea of ever engaging in the practice of medicine myself. It was merely a measure of self defense against the evils of disease, and a false science. Accordingly, when I had closed up my business of the season, I called on Dr. Benjamin Thomson, who kept an infirmary in Charles Street in Boston, and acquainted him with my wishes. He expressed a strong desire that I should remain with him and become his assistant in attending the sick, which I consented to do.

This Thomson of whom Brown is speaking was not the originator of the Thomsonian System, but must have been his son, as Brown speaks of him as owning the patent on the method. The originator of the system was Samuel Thomson, born in Alstead, New Hampshire, in 1769, a self-taught herbalist who used steam baths and strong emetics such as *lobelia inflata*, bayberry, and cayenne to cure his patients. Thomson strongly believed that regular doctors had killed his mother and brought his wife to the brink of death, and began his botanical practice of medicine to counteract the evils perpetuated by mineral medicines, thereby starting a feud which lasted long into the nineteenth century.

This was the system with which John A. Brown allied himself. He tells of his initial fears when seeing patients *in extremis* at the Thomson infirmary, wondering how they could possibly tolerate doses of lobelia and time in the steam box, and then see them enjoying a hearty meal around the table later in the same day. Brown continued with Thomson for a few months, and then decided to open his own infirmary on Tremont Street with a partner, buying their drugs from Thomson. Then, when he found partnership not congenial, Brown started his own business on Washington Street, which he styled the Massachusetts Thomsonian Infirmary.

The time came when he grew dissatisfied with the need to buy medicines from Thomson at an enormous markup in order to legally call himself

a Thomsonian physician. He had spent $700-800 in one year for materials he knew from having worked with Thomson to have cost about $120. Thomson would not relent on his mark-up, so Brown broke with him. The unpleasantness caused Brown to decide to leave Boston and begin in a new area. He chose Pawtucket, Rhode Island, and moved there in about 1836.

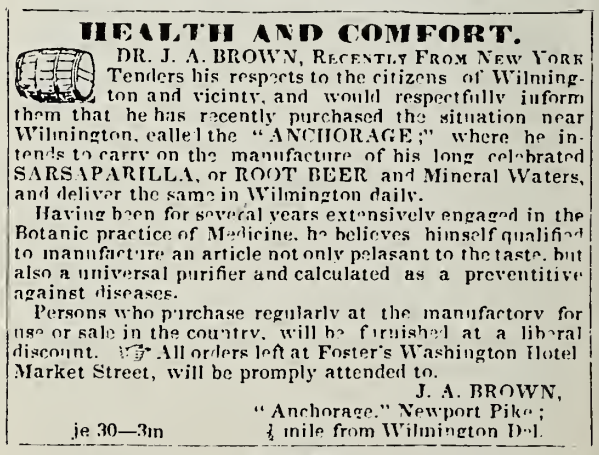
All his medical adventures in Boston occupied only about two years, from 1834-1835, when Brown was 24 and 25. He was 26 when he moved to Pawtucket, where he founded the Rhode Island Botanic Infirmary. Later, this was relocated in Providence. Through this move, Brown placed himself in the middle of a great upheaval in the history of Rhode Island, and opened a new chapter in his life.

For a few years some of the citizens of that state had been chafing under the restrictions of the old Charter of 1663 from King Charles II, which was still in force. The most galling provision was that only landholders and their eldest sons could vote. Rural areas had the greatest representation in the state legislature, even though cities had the largest populations. Certain interests wanted this law to be changed, and a political struggle began. In addition to successfully running his Pawtucket Infirmary and manufacturing a medicinal root beer, Dr. Brown joined the political struggle, on the side of change.

In 1840 he began a newspaper which tried to win converts to the new ideas. Since he was busy with his practice, he hired Charles T. Congdon, who later became a career journalist, to run the paper. Congdon, in his autobiography *Reminiscences of a Journalist*, tells of those days:

> The year 1840 was one of great political activity everywhere, and the contest in Rhode Island was a particularly lively one. People who could not vote more than ever envied those who could. In a desperate minority, the Democrats were anxious for a good cry. But the movement which was to grow to such considerable proportions had a personal and somewhat insignificant beginning. There was a Dr. John A. Brown, a botanical physician, who supplied the people of Providence with root-beer of a pleasant and salutiferous quality. Brown's beer was in demand, and being of a foamy and effervescent sort, it may have had something to do with the ebullitions which followed. At any rate, when not engaged in building up the constitutions of his patients, the doctor was painfully sensible that the ancient State had no Constitution of it own--a deficiency which, both as a patriot and a practitioner, he ceased not to lament. He determined to start a free-sufferage agitation; secondly, he resolved to emit a free-sufferage newspaper; and thirdly, he employed me to edit it. He might have done better if he had been able to offer a little higher wages; for I engaged to convulse Rhode Island (with the Plantations thrown in) for the modest remuneration of five dollars per week. A name was wanted for the journal, and I suggested "The New Age" as expressive and appropriate, particularly as we proposed to abolish the work of an age which might be considered an old one. So the first number of the newspaper was issued from a little office which had just about type enough to set up a single edition. For some time the public paid but little attention to our denunciations of Charles II and his musty old charter; but Dr. Brown was not in the least discouraged, and I am sure that I was not. The doctor, I knew, was delighted, for the beer business was, in two senses, lively, and he could afford even the expensive luxury of printing a newspaper without subscribers or purchasers. He was an extremely good-natured man; and the town in Delaware to which he removed... after the troubles, made him a member of the Legislature.

The Rhode Island issue could probably have been settled peaceably, but a leading light in the movement for change was Thomas W. Dorr, who



HEALTH AND COMFORT.

DR. J. A. BROWN, Recently From New York Tenders his respects to the citizens of Wilmington and vicinty, and would respectfully inform them that he has recently purchased the situation near Wilmington, called the "ANCHORAGE;" where he intends to carry on the manufacture of his long celebrated SARSAPARILLA, or ROOT BEER and Mineral Waters, and deliver the same in Wilmington daily.

Having been for several years extensively engaged in the Botanic practice of Medicine, he believes himself qualified to manufacture an article not only pleasant to the taste, but also a universal purifier and calculated as a preventitive against diseases.

Persons who purchase regularly at the manufactory for use or sale in the country, will be furnished at a liberal discount. ☞ All orders left at Foster's Washington Hotel Market Street, will be promply attended to.

J. A. BROWN,
"Anchorage," Newport Pike;
je 30—3m ¼ mile from Wilmington Del.

FIGURE 1
Dr. Brown's advertisement in local paper.

felt violence was the only way. In 1842 he and a few armed followers tried to capture an arsenal using a cannon, and when it would not fire, they withdrew. Another attempt on Dorr's part to rally men to his cause and fight against the state militia ended bloodlessly. This tempest in a teapot was labeled Dorr's War, or the Rhode Island Revolution, and it did have the effect, perhaps along with Brown's newspaper, of causing the adoption of a new state constitution in 1842, which gave voting rights to native born Rhode Island men of legal age who paid taxes of $1 per year or served in the Militia; also it increased city representation in the legislature.

Somewhere between this time and 1849, Brown left Rhode Island for New York City. His autobiography, written while he was in Rhode Island, does not tell us why he decided to move, and we do not know if he set up a clinic in the new location. The medicinal root beer manufacture was continued. In the late 1840s he decided to settle further to the south, and selected Wilmington, Delaware.

Captain John Gallagher, a prominent American Naval officer during the War of 1812, lived in retirement in Wilmington in a home appropriately named The Anchorage. After Captain Gallagher's death, his heirs sold the house and its adjoining 100 acres to Dr. Brown. From this point on, Dr. Brown gave up his botanic medicine practice, except for continuing in the root beer business, and became a gentleman farmer. He advertised in local papers when he first arrived in Wilmington (Fig. 1). He became a trustee of the poor, and was a member of the committee responsible for the upkeep of the County Alms House.

In 1856, Brown decided to sell the mansion house and part of the land, probably to raise money for another project he had in mind. The new buyer only took 8.2 acres out of the 100, and Brown located to another part of the land. A large project of his, completed in 1860, which is why I think he needed to sell his home, was the erection on his land of what he called the Living Home for the Sick or Well, and the Delaware Home for the Insane.

His advertisement for patients after the Home had been in operation for two years showed a drawing of a large building with several outbuildings (Fig. 2), and points out that the sick or well could find a home there and that unfortunates no longer need go to the County Alms House. The home for the insane was said to equal in usefulness the much more expensive institutions in other states. Dr. Brown entreated the people in turn to urge the legislature to establish a hospital of suitable size for the insane for the entire state, and so was a forerunner in this important movement.

Dr. Brown also set up a retirement home, advertising its existence, along with his credentials, on post cards (Fig. 3). His statement on the post card about being a Southern sympathizer must refer to his belief in the right of the South to secede, since he did not believe in slavery. He was, in fact, a proponent of black rights in a time when theirs was anything but a popular cause. He gave part of his land for a black settlement which he named New Liberia, and was later a champion of theirs in the Delaware legislature. He owned land near Petersburg, Virginia during the war, possibly to be a place to which he could remove if his neighbors got unfriendly, but there was no need to take advantage of this.

Dr. Brown laid out streets on part of his land, and the part of Wilmington which developed there is called Browntown to this day. He also operated a hotel on his property in the late 1860s, called the Sixth Avenue House. In 1867 he tried unsuccessfully to sell it by an ad in the *Delaware Gazette*, describing it as four stories, 50 rooms, with a ten pin alley, sale or let, "as the proprietor's health requires a change."

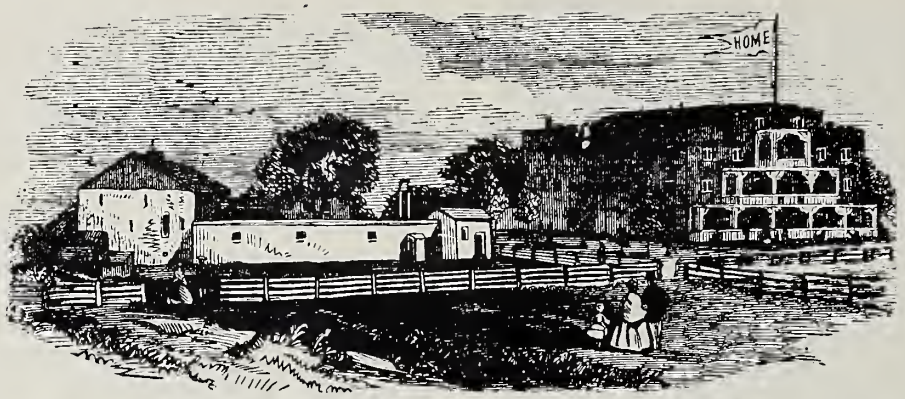
Dr. Brown, a lifelong Democrat, ran for and was elected to the Delaware House of Representatives in 1868 for a two year term. One of his acts there seems to have been done without consulting his constituency, for in March, 1869, the local newspaper stated:

> Dr. Brown of Wilmington has, it appears, got himself into something of a fix by having a bill passed in the House to incorporate his home area, West Wilmington, the people there not desiring the same.

How he extricated himself from this I have not learned.

Dr. Brown was the chairman of the subcommittee on State Property, which tried to learn if the state or the county owned the State House in which the Senate and House met. He reported back to the House,

> Your committee begs leave to report that, after a long and patient inquiry, your committee has been unable to ascertain that the State of



Living Home for Sick or Well, Wilmington, Del. Dr. J. A. Brown.

The above institution has now been in operation for two years with as much success as could reasonably be expected by a new and individual enterprise, without any public patronage. The proprietor would express his thanks to the community generally for their kind *wishes* for its success, and particularly to those who have used their influence and patronage in its behalf. There being no other place in the State except the County Alms House where he

UNFORTUNATE CAN FIND A HOME,

Induced the proprietor to make it of that general character that would meet the wants of the community generally.

AS A HOME FOR THE SICK,

It is unlike any other institution, either public or private, as the patients have the choice of any treatment they prefer,

With Proper Nursing.

The department for curable or moderately insane, has received a fair share of patronage, and several have entirely recovered; while others, now inmates and supposed incurable, by kind treatment seem contented and require but little restraint. This department is the most important to the community as it provides a HOME for a class of unfortunates that cannot be properly provided for at their own homes. A very large proportion of the insane are persons of moderate means, while some are paupers. Most of the States have spent large sums in erecting institutions for their relief. Should not this State do something for them? They have heretofore been entirely overlooked and suffered to drag out a miserable existence, shut out from all society, or at best to be provided for as best they may in the County Almshouses. The State already provide for the very worthy but much less needing classes, viz: The Deaf and Dumb, the Blind, and Idiotic. With a reasonable assistance from the State, I will make the

HOME FOR INSANE

equal in usefulness to the much more expensive institutions in other States. Will the people urge the subject upon their servants, who will constitute the next Legislature? If so and they do their duty, as undoubtedly they will

The Delaware Home for Insane

will be firmly established.

J. A. BROWN,
Proprietor of The Living Home and the Delaware Home for Insane.

oct17.

FIGURE 2
Dr. Brown's Living Home.

Delaware has any legal claim to any portion of the buildings commonly called the State House, situated in the town of Dover, and that the joint occupation of the buildings with Kent County is on sufferance, having no claim or right except those created out of the fact of general usage. As a proof of this it is reported as a fact that at a time in a former generation, the Sheriff of Kent County, for some cause which your committee has been unable to learn, did actually enter the building with drawn sword, and then and there disperse the Legislature then in session, and it completed its session elsewhere. This being the situation of the subject under consideration, your committee is of the opinion that it is quite time that some course should be adopted with a view to provide, at no distant day, such accommodations for the use of the state as shall be an honor to the state, and enable her servants, the representatives, to enjoy such accommodations as every housekeeper provides for himself and family at his own homestead.

Later in the session, the newspaper quoted Brown concerning a cause he believed in.

> On Thursday last in the House of Representatives at Dover, Dr. Brown of Wilmington offered a bill allowing colored persons to be taxed for school purposes. Of course, it was lost, but it shows that the "advanced ideas" are still advancing. Two years ago the Legislature would not have allowed the bill more than a first reading, but what may be done in two years hence may be inferred from the remarks of Dr. Brown. He spoke at some length in favor of the bill. He advised his fellow members that they must meet the issue sooner or later, and he thought it more manly to meet the question

DR. J. A. BROWN, native of Massachusetts, and founder of the *Tremont and Massachusetts Thomsonian Infirmaries in Boston*, afterwards the *Rhode Island Infirmary* in Providence, and ten years extensive practice in that State ; the originator of the celebrated 1776 *Root Beer*, which, under his supervision, was extensively manufactured in Providence, Boston, New York, Philadelphia, Baltimore, and other small villages ; one of the principal actors in the Rhode Island Revolution, being owner of a Printing Office, Proprietor and Editor of the paper called the *New Age*, which had much to do with giving to that State a Constitution, in place of the old, worn out Charter from the English King, Charles the Second.

In 1849 I located near Wilmington, Del., as an Agriculturist, as I still am. Though the city has now occupied some twenty acres of my place, I yet have some fifty acres left.

In 1860, I built what I named THE LIVING HOME, (some 50 rooms) and for some years had the care of the sick of the Union army, and perhaps thereby escaped arrest, as I was well known to be a Southern sympathizer. Age admonishes me that my active days are nearly spent, and I now propose that my establishment shall be a HOME for myself and wife, with such others as are able to pay, but do not wish the trouble of servants, or being beholden to children while waiting for their final passage over the river. In short. A HOME for such as have made the world better for having been in it.

Charges according to ability to pay.

P. S.—Moderate Winters, plenty of Shade, and Comfortable Summers.

FIGURE 3

Post Card Advertising Dr. Brown's Living Home.

like reasonable persons, devoid of prejudice. He could not see why there should be any prejudice against the colored race, as they were harmless and very quiet when not interfered with by "carpetbaggers" and "scalawags." He would go as far as anyone to drive out of their midst those who come here simply to stir up strife and dissention. He urged the members to send the bill to the Senate. However, it was defeated by a vote of 15 to 4.

After his stint in the House, Dr. Brown had one more venture into the political arena. There was so much corruption during the first presidential term of Republican Ulysses S. Grant, that by the time of the 1872 primaries, liberal Republicans who were against Grant sided with the majority of the Democratic Party and selected as their candidate Horace Greeley, the famous editor of the *New York Tribune*. A portion of the Democratic party could not stomach a coalition with anyone faintly Republican, and so formed their own splinter group, called the Straight-Out Democrats. Dr. Brown was one of them. At their national convention in Louisville, Kentucky, he was one of the two delegates from Delaware. The Straight-Outs nominated a prominent New York attorney, Charles O'Conor, as their candidate.

Did O'Conor have any chance of winning? Here is what a leading Pennsylvania Democrat, D.G. Bush, said when declining an invitation to attend the Straight-Out Convention:

> No person outside of a lunatic asylum can imagine that the nominees of the Louisville Convention could, by any possibility, be elected. The only object therefore, in holding that convention, is to distract our party, direct votes from Greeley, and thereby directly assist in the reelection of Grant.

U.S. Grant won the election handily, and a united Democratic Party would not have prevented it.

Dr. Brown died in 1874 while on a trip to Boston, the city which played such a part in his early "medical" career. His obituary in the Wilmington paper said:

[Dr. Brown] was well known here as a somewhat eccentric but enterprising liberal citizen. He had been laboring at his farm for about two weeks, and complained of being unwell. A week before his death he went to New York, became sick there with a chill, but, recovering somewhat, went on to Boston, where he was suddenly stricken and died on July 19. He leaves a wife and six children. Interment will be in Riverview Cemetery, Wilmington.

Reference

1. Brown JA. The family guide to health, containing a description of the botanic Thomsonian system of medicine, with a biographical sketch of the author. 1837, Providence, Rhode Island, B.T. Albro, Printer.

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4:00 to 5:00	Case presentations - Walter R. Hepp, M.D. Panel discussion - Norman Feinsmith, M.D., Leonard N. Horowitz, M.D., Terry Langer, M.D., Jan R. Weber, M.D., Adrian S. Weyn, M.D.

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ACCEPTANCE OF MATERNAL ALPHA-FETOPROTEIN SCREENING IN WILMINGTON HOSPITAL'S OBSTETRICAL CLINIC

Karen Byrne-Essif, M.S.
John M. Naber, M.S.
Garrett H.C. Colmorgen, M.D.

Introduction

During pregnancy, limited amounts of alpha-fetoprotein (AFP), a substance found in fetuses throughout pregnancy, cross the placenta and enter the maternal bloodstream. In the case of a pregnancy with an open neural tube defect, the amount of maternal serum alpha-fetoprotein (MSAFP) is usually significantly elevated. Screening for MSAFP can detect about 85% of fetuses with open neural tube defects. In addition, other poor pregnancy outcomes such as fetuses at increased risk for anterior abdominal wall defects and certain chromosomal abnormalities can also be anticipated with MSAFP screening. The test for MSAFP is designed to be performed between the fifteenth and twentieth weeks of gestation.

Encouraged by the May, 1985 "Alert" of the American College of Obstetricians and Gynecologists concerning the potential liability of not offering this screen, many obstetricians are now offering MSAFP screening. Screening for MSAFP has been found to be an effective screening tool with a favorable cost-benefit ratio.[1] However, in order to avoid unnecessary patient anxiety,[2] and false global assurance of a normal pregnancy outcome with negative test results,[3] the multistage screening protocol must include appropriate patient education.[4]

In March, 1986, a MSAFP screening program was implemented at the Medical Center of Delaware's Wilmington Hospital obstetrical outpatient clinic. The program consists of patient education, the signing of an informed consent/refusal form, and an order from a physician for the blood to be drawn if the patient agrees to the procedure. All patients are given an explanation of their results as soon as they are available. Patients with abnormal results receive the follow-up services of additional genetic counseling, ultrasound examination, and if appropriate, amniocentesis.

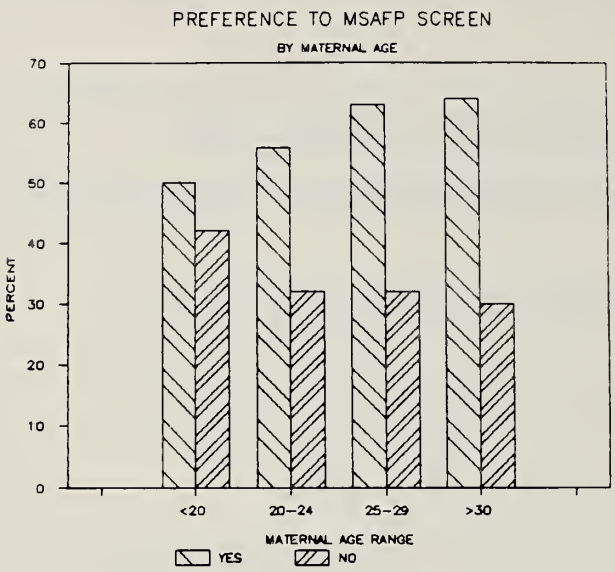
Initially, one-on-one counseling with poster cards was used. However, beginning in 1987, a slide-tape program was used to supplement patient education. With the revised format, the genetic counselor briefly explains the purpose of the test, shows the slide-tape program, answers any questions, and then obtains the patient's signature on the informed consent/refusal form.

This study was designed to determine the acceptance of MSAFP screening according to maternal age, race, and method of counseling.

Ms. Byrne-Essif is a senior genetic counselor and faculty member of the College of Medicine at the University of Arizona.

Mr. Naber is the Newborn Screening Coordinator with the Michigan Department of Public Health in the Genetic Services Program.

Dr. Colmorgen is the Director of Maternal-Fetal Medicine of the Department of Obstetrics and Gynecology at the Medical Center of Delaware. He is also an assistant professor of Obstetrics and Gynecology at Jefferson Medical College in Philadelphia.



Materials and Methods

Of the 753 patients who received genetic counseling through the MSAFP screening program from March 1986 through July 1987, six were not candidates due to gestational age beyond 20 weeks. The remaining 747 patients were coded and entered into a microcomputer for analysis. Maternal age data was combined in five year age groups and the mean age in each category was calculated. For this study, the variables mentioned were analyzed with regard to the preference for the MSAFP test at the time patients were counseled. Heterogeneity chi-square and Pearson's correlations were used to test for significance within these variables. The statistical analyses did not include the category of women uncertain about having the test, since their numbers were small.

Results

From the maternal age data it was found that as maternal age increased, acceptance of the procedure increased, and the number of refusals decreased (Fig. 1). Only the decreasing number of refusals were found to be significantly correlated (p less than 0.05) with increasing maternal age.

When preference for the MSAFP test was compared between whites and nonwhites, there was a slightly higher acceptance among whites (Table 1); this difference, however, was not statistically significant (p less than 0.05).

Finally, acceptance of the MSAFP test was compared by whether a patient was educated by the genetic counselor or by the slide-tape presentation. Again, there was no statistically significant difference in the acceptance of the procedure (p less than 0.05). However, it is interesting to note that twice as many patients were uncertain about having the test after the slide-tape program as after the genetic counselor's presentation.

Discussion

As a woman gets older, there is greater acceptance of MSAFP testing (Fig 2). A report by the National Center for Health Statistics noted the current trend for well educated women to delay motherhood.[5] Once pregnant, they tend to seek prenatal care in the first trimester. Educated women tend to learn of prenatal tests and the risks of birth defects by reading as opposed to physician counseling.[6] Thus the older, better educated group is probably aware that older pregnant women face a higher risk of bearing children with genetic disorders. In addition, older women are more likely to present for early prenatal care. Therefore, they are more likely to take advantage of prenatal tests, such as MSAFP screening and amniocentesis.

Time saving counseling techniques are important in an area where there is a paucity of genet-

TABLE 1
Preference to MSAFP screen by race.

	YES	NO	UNCERTAIN
WHITE	223 (58%)	128 (34%)	31 (8%)
NONWHITE	190 (53%)	148 (41%)	20 (6%)
UNKNOWN	3	3	1
TOTAL	416	279	52

TABLE 2
Preference to MSAFP screen by informant of test

SOURCE OF INFORMATION	YES	NO	UNCERTAIN
GENETIC COUNSELING	248 (57%)	164 (38%)	21 (5%)
SLIDE—TAPE	168 (54%)	115 (36%)	31 (10%)
TOTAL	416	279	52

ic counselors. A slide-tape program conserves time and insures that patients are given consistent information.[7,8] No significant differences have been found in the patients' learning, satisfaction, or anxiety.[6,7] A similar study of a beta-thalassemia counseling program also found no disadvantages.[8] In other studies, amniocentesis patients receiving an audiovisual presentation had increased understanding of the risks and benefits of the procedure.[6,9] In the present study, no differences in acceptance of MSAFP screening were revealed between the women who had viewed the slide-tape program and those who had not. No racial differences were noted (Table 1).

Conclusion

An audiovisual presentation is an effective method of assuring that all pregnant patients receive complete and accurate counseling. We found that patients who viewed the audiovisual presentation were more likely to be uncertain about the MSAFP determination than those exposed to one-on-one counseling. Due to this uncertainty, we recommend that personal counseling be available to address patients' questions and concerns.

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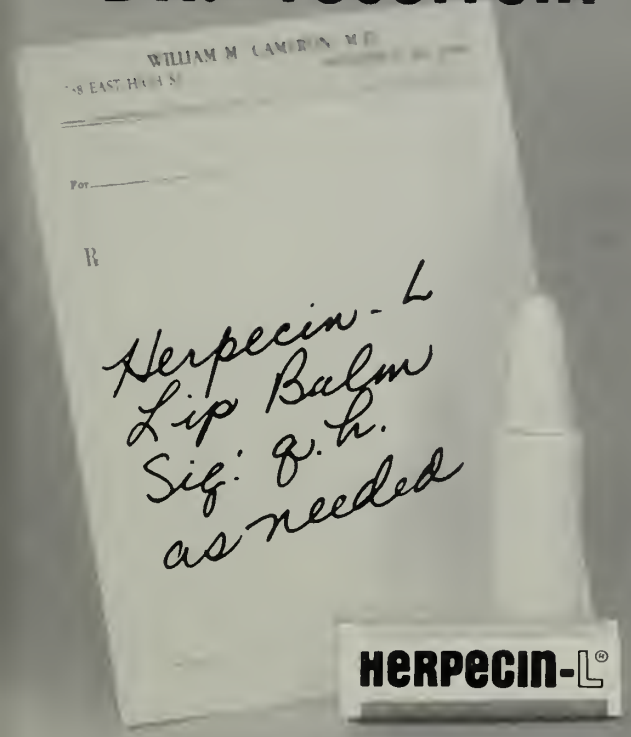

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LUNG CANCER IN RUBBER MANUFACTURING WORKERS: TWO CASE REPORTS

Rosemary K. Sokas, M.D.
Thorne Sparkman, Jr., M.D.
Walter J. Levinsky, M.D.

Introduction

Workers in the tire and rubber manufacturing industry are exposed to a variety of substances such as acrilonitrile, chloroprene, and styrene-butadiene, which are suspect carcinogens in the monomer form, but are not regulated as such in the polymer (solid) form.[1-4] However, monomer traces are often measurable in the solids and concern has surfaced regarding the leaching of trace carcinogens from finished products such as infant pacifiers. Surveys of workers in this industry have reported an excess of deaths from lung cancer, generally in areas of higher temperatures (130°C) such as molding, curing, autoclave or pressing.[5-7] Both smoking and non-smoking rubber workers have demonstrated increased urinary mutagenic activity by Ames testing when compared to non-occupationally exposed controls, with a synergistic effect between smoking and occupational exposure suggested.[8] Similarly, urinary thioether levels in rubber workers decline initially, followed by a rise after approximately one month of exposure, as would be expected with acute exposure to alkylating agents followed by eventual metabolic pathway induction.[9]

This information suggests that workers engaged in various rubber manufacturing activities need improved industrial hygiene measures to prevent worker contact with known carcinogens. It also suggests that issues of widespread environmental importance may be identified by close attention to workplace outcomes of exposure. We report three cases of lung cancer that occurred in two men working in the same small rubber pharmaceutical manufacturing plant.

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Dr. Levinsky is a clinical professor of Medicine at Temple University, Philadelphia.

Case Reports

Case 1

A 44 year old man was seen for rib trauma in December, 1973, and found to have a left upper lobe lesion on chest roentgenograms. Tomography was consistent with granulomatous disease. In December of 1974, he complained of hemoptysis, weight loss, and left-sided chest pain. A chest roentgenograph revealed a four-to-five-fold increase in the left upper lobe lesion. Bronchoscopy and sputum cytology showed an oat cell carcinoma. He received full course radiation therapy and combined chemotherapy with cyclophosphamide, adriamycin, and DTIC.

In March, 1977, the patient developed congestive heart failure, attributed to the adriamycin therapy. A new right hilar mass was detected in October, 1978. Bronchoscopy revealed a fungating tumor shown by biopsy to be squamous cell carcinoma. He was hospitalized again in April, 1979, and died at the age of 50.

The patient had a 30-60 pack/year smoking history, and had worked from September, 1952 until December, 1974 in a small factory that produces pharmaceutical rubber products. All processes took place in a room approximately 60 x 40 x 13 feet. For the last 15 years of employment he worked as a mixer, blending the various rub-

ber formula ingredients on an open roll mill. The various components, which included polymers of acrilonitrile, chloroprene, and styrene-butadiene among others, were blended in the mixer, then extruded, pelletized, and molded into the finished product, which was then vulcanized. The room is described by co-workers as having been so dusty that visibility was limited to 15-25 feet. Each batch of material required approximately a 35 minute mixing cycle and the patient mixed an average of 12 batches daily. He and others complained of eye, nose, and throat irritation, depending on the ingredients mixed. Ventilation appears to have been limited and the patient and co-workers used handkerchiefs to provide some respiratory protection. An odor of hot rubber was usually present.

In January, 1980, the Occupational Safety and Health Administration (OSHA) performed a "wall-to-wall" inspection of the plant in response to a noise complaint. During this inspection, the highest temperatures noted were in the molding presses, which reached 300° F. Because this temperature is not sufficient to cause polymer degradation, it was concluded that a carcinogenic hazard did not exist. Recommendations for improvements in ventilation were made.

Case 2

A 32 year old man presented in September, 1982, with vomiting and weight loss. He had a right upper lobe infiltrate with paratracheal adenopathy on chest roentgenogram. A left supraclavicular lymph node biopsy revealed undifferentiated adenosquamous carcinoma with a mucin producing cell type. A bone scan, CT head scan, and liver scan were all positive for metastatic disease. The patient died in November, 1982.

He had smoked a total of 15 pack years of cigarettes, and his past occupational history included four years of employment in a book bindery where he worked at a machine folding papers into pages, with some exposure to paper dust. After closure of that plant, he began to work in the rubber pharmaceutical factory where he worked from age 23 to age 32, initially as a general plant laborer, then spending seven and a half years as a painter in the plant. When working close to the various production processes, he noted frequent eye irritation and occasional nose and throat irritation which would last several months, depending on the production process. The atmosphere was dusty, and he brought dust home on his work clothes, although improved ventilation and equipment lessened this problem during the last year and a half of his employment. In addition to the exposures described above, he worked with various paints and kerosene, and would occasionally wear a cannister face mask for "harsh" paints, reducing but not eliminating various odors.

Discussion

Lung cancer, the most common cancer in adult men, is also the most common malignancy related to environmental exposures. Because the cases reported here are unusual in age of presentation and occurrence of a second lung primary, they signal a warning concerning potential inhalational exposures. Both of these patients presented with lung cancer at ages earlier than might be expected from their smoking histories. The first patient died from a second (metachronous) lung primary at the age of 50. Lee, et al, reported multiple primary malignant tumors in 0.8% of 8428 autopsies; age at time of diagnosis of second primary malignancy in this series was 60.92 years, with a 95% confidence interval of 57.16 to 64.68 years.[10] The second patient died at age 32, well within the lowest fifth percentile for lung cancer deaths among cigarette smokers.[11] The development of metachronous primary lung carcinomas in the first patient is itself unusual, although the incidence increases with prolonged survival after first primary.[12-19] Cigarette smoking and asbestos exposure appear to be associated with the development of multiple primary malignancies, but the role of other environmental factors is unknown.

These cases serve to redirect attention to an industry where the question of carcinogenic exposure has been raised but not answered. The manufacture of tires and smaller synthetic rubber products entails the use of many of the same components, including polymers, antioxidants, and curing agents, and both processes and temperatures are similar. The monomer forms of several of the polymers used in rubber manufacturing are considered potential human carcinogens based on preliminary epidemiologic data as well as animal carcinogenic and mutagenic data. Because there may be monomer residues present on the polymers used in rubber manufacturing, these risks may be relevant to rubber workers.[21]

Federal regulations and enforcement as demonstrated by the 1980 OSHA inspection reported here, do not address the issue of possible carcinogen exposure in this setting. This is hardly surprising, since asbestos, one of the most convincingly studied carcinogens known was regulated for its fibrogenic rather than carcinogenic properties until 1986.

Large scale epidemiologic studies of potential adverse health effects have already been done, with results that are suggestive but not conclusive. These studies have been conducted in major manufacturing plants with active industrial hygiene and safety engineering departments;[5,6,20] these plants are generally much cleaner than small plants which often cannot afford such services. It may well be that identification of suspicious clusters in small industry could lead to Health Hazard Evaluations of precisely those plants where exposure is greatest.

Epidemiologic surveys investigating the work-relatedness of disease face several difficulties. Only 12 of the 50 states routinely code "usual occupation" and "usual industry" on death certificates.[22] Of those that do, a significant fraction of responses are unusable ("retired" or "unemployed") or incorrect.[23] Even when correctly provided, information on "usual occupation" overlooks entry level jobs, generally the dirtiest, and may thus obscure associations with long latency periods. Rutstein has proposed a list of ICD coded illnesses that serve as Sentinel Health Events (Occupational). These provide the impetus for epidemiologic or industrial hygiene studies, or serve as a warning signal that materials substitution, engineering control, personal protection or medical care may be required.[24] Lung cancer is always a "sentinel event," and occurrence at an earlier than expected age, or occurrence of metachronous primary lung cancers should signal an additional warning.

This information, requiring a clinical suspicion of exposure-outcome, depends on occupational history-taking, since diseases such as lung cancer are otherwise indistinguishable from diseases of non-occupational origin. Despite this, occupational exposures are mentioned only rarely in case reports in the oncologic literature.[14,25] Most case studies provide no environmental information beyond the smoking history.[17,18] This oversight in the case report literature is confirmed by chart reviews that document inadequate occupational information among faculty as well as housestaff in teaching hospitals.[26]

In the cases presented in this paper, clinical suspicion proved difficult to translate into epidemiologic study, however. The manufacturing plant itself was not interested in pursuing investigation of possible exposure-related cancers. The union president, who was concerned with health and safety issues in general, initiated the 1980 OSHA investigation, but was voted out of office shortly thereafter, and the union membership was reported to be less concerned with possible health hazards than with the prospect of the plant closing and reopening elsewhere. The physician is not able to initiate requests for evaluation by NIOSH (National Institute of Occupational Safety and Health), which presents a problem in that in precisely the most worrisome situations the patient may be too ill to initiate or pursue such a request. The physician is able to request assistance from municipal and state health departments, as was done with these cases. However, varying capabilities and limited access to workplaces often limit epidemiologic investigation under these circumstances.

Summary

The cases described here raise two issues for discussion in the field of Occuaptional Health:

First, current regulations monitoring exposure to the polymers of suspect carcinogens may be inadequate, particularly in the rubber manufacturing industry. Further epidemiologic investigation is needed to investigate this, and methods of targeting and gaining access to appropriate populations may need to be developed. Second, methods for collecting clinical information of potential relevance and for pursuing workplace investigations based on clinical concerns need to be developed and made accessible to the practicing clinician. It is unlikely that further education of health care providers in the importance of occupational history-taking will have lasting effect in the absence of timely, accessible, and responsive reporting systems.

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Acknowledgments

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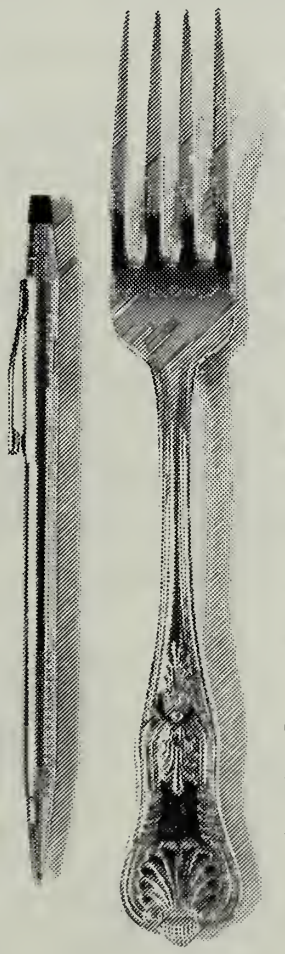

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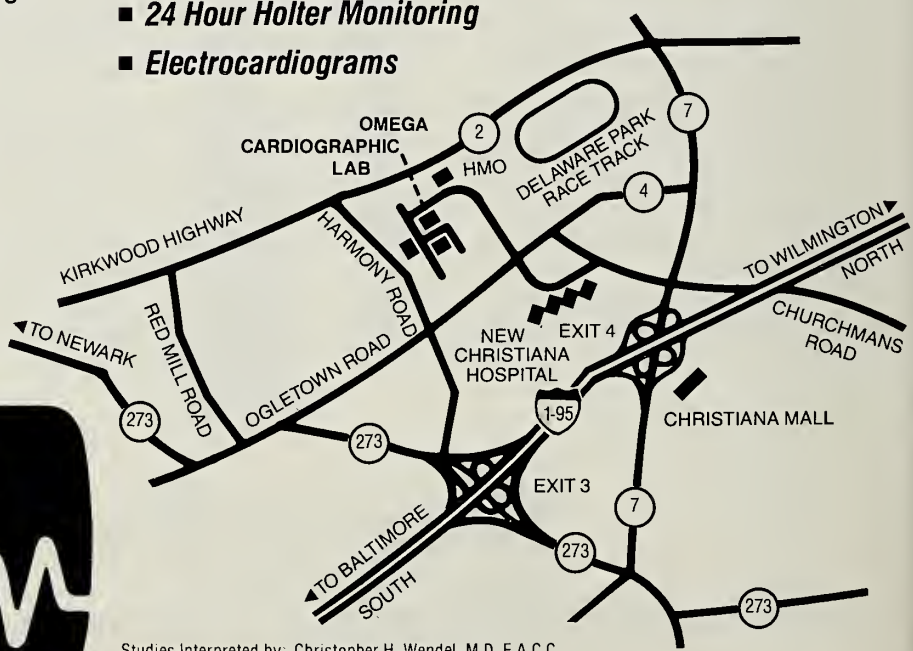

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Medical Ethics

ALLOWING THE DYING TO DIE

Many physicians believe that if human beings did virtually everything they are supposed to do to stay as healthy as possible, with a little bit of luck they would live out their lives virtually disease-free and would fulfill their genetic capabilities for longevity.

Of course, the "clock" would eventually begin to run down toward the end of the normal life span, and the person would die. There is little question that a human being is not likely to survive until age 200. Somewhere beyond age 70 is considered likely today, and most of the avant garde in medicine believe that 110 to 150 years is probably the maximum human genetic capability for life expectancy.

However, we are all not breathing, drinking, eating, exercising, and making proper agreements as we should. Some of us do have health problems or may experience life-limiting accidents, and chance encounters with potent diseases do exist. As a result, we all may not fulfill our full genetic complement of years. Hence, the issue of untimely death is very real to all of us and, in particular, to physicians.

Traditionally, physicians have borne the brunt of making the fateful decision as to which patient should go on living, though in need of temporary help, and which patient, though artificially supported, is in an irreversible process of dying. The whole "ethical" issue of whether to continue or to terminate life support systems, therefore, has focused on the doctor's ability to distinguish, with adequate certainty, between those who may live and those who are clearly dying.

Unfortunately, we are living in a period of medical care luxury. In wartime or during a natural disaster, triage is carried out automatically, without introspection. However, in the absence of any overwhelming demands on the health care delivery system, we make blanket efforts to support as many lives as we can. Some patients obviously do not make it, but many others who should be allowed to die are not let go in a timely fashion.

No one is perfect, and none of us is God. As physicians, we have made, and will continue to make, mistakes. But the issue is one of choice as to who should live and who should die, and everyone has interests in the decision. Sometimes the interests--representing religion, the law, medicine, the family, business, and of course, the patient--conflict.

Unfortunately, medicine has allowed itself to

become confused and to take on the demeanor of a follower. We have become afraid of the law and of our responsibilities. I'm not so foolhardy as to imagine that we can automatically make the right decision--immune from criticism. But how many times have we seen those patients, who we know are about to die, continue to receive life support because another physician, in his discussions with the family, made it seem as if there were an acceptable chance for survival and recovery? How often have we heard, "we should do everything we possibly can"?

It's sometimes difficult to differentiate the living from the nearly dead or dying, but it's a decision for which we're responsible. It's time to take this decision making process back from the courts--without self-immolation.

Our own interests and our lack of courage have made us all afraid to pull the plug, turn off the switch, disconnect the respirator, stop dialysis, pull the feeding tube, or, for that matter, even discuss these possibilities with the patient's family as we should.

There may be a fine line crossed by those who seem too eager to end the "suffering," but most of the people who have been accused of euthanasia, both physicians and the public, have acted only out of humanitarian interest. Life or death in the absence of God's visible intervention has been, and should continue to be, a humane decision. And we physicians must not fail to accept that responsibility.

Not like cruel exterminators but like defensive protectors of reality, we should use our skills to recognize the living from the obviously dying.

H. Robert Silverstein, M.D.

Dr. Silverstein is a board certified cardiologist in private practice in Hartford, Connecticut. He is also a clinical assistant professor of Medicine at the University of Connecticut School of Medicine. Reprinted with permission from Medical World News, June 8, 1987, page 124.

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Editorials

POSTTRANSFUSION HEPATITIS

The greatest risk in transfusing blood and blood products is the transmission of communicable disease to the recipient. Each unit of donor blood is tested for hepatitis B, syphilis, and AIDS, but no test is available for non-A non-B (NANB) hepatitis.[1,3]

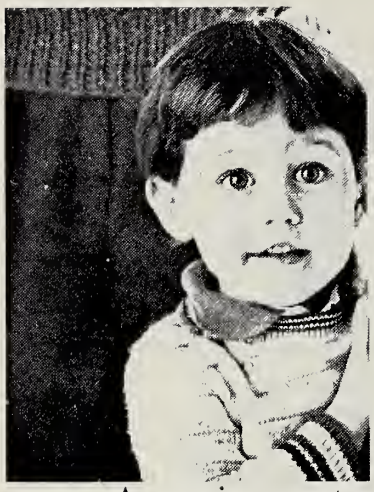
Posttransfusion hepatitis is diagnosed by "two consecutive blood samples within a 14 day period in which the ALT (SGPT) levels were elevated (one level greater than 45 IU/L, the other greater than 90 IU/L). Elevations must have occurred from day 11 to day 180 after the first transfusion." The incidence of posttransfusion non-A non-B hepatitis ranges from 4.7 - 17.5%, and the most common agent in posttransfusion hepatitis is NANB hepatitis.

Non-A non-B has an indolent course. Victims' usual complaints are fatigue and anorexia. The peak incidence is seven to eight weeks after transfusion. Of the patients, 75% are anicteric; a fulminant course is unusual. However, 50% of patients with NANB hepatitis have abnormal liver tests for longer than one year, and 20% progress to cirrhosis.

To date, no specific marker has been found to identify NANB hepatitis. It was first noted by chance that units of blood positive for antihepatitis B core antigen are associated with a two- to three-fold risk of NANB hepatitis developing in the recipient, and an elevation in the ALT (SGPT) is also associated with an increased risk of NANB hepatitis. It is predicted that eliminating from transfusion units positive for either marker will result in a 20 - 30% decrease in NANB hepatitis.

The Blood Bank notifies donors only when their ALT is elevated at least two times higher than normal. It is not uncommon for an anxious donor to contact his physician's office concerned because the Blood Bank has informed him that his liver tests are abnormal. In several large series, when asymptomatic donors with abnormal ALTs were examined, obesity was responsible for almost one quarter of the abnormal liver tests, alcohol for 5 - 15%, medication and exercise for 3%, and it was estimated that from 20 - 67% had NANB hepatitis. However, there are many other causes of liver disease, such as industrial exposure to toxic chemicals.

It is important that we as physicians completely evaluate any patient found to have an elevation in ALT (SGPT). Such a patient should have a complete profile of liver tests and be screened for all hepatitis markers. An occupational histo-



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ry, and history of exposure to drugs should be taken, remembering that salicylates, acetaminophen, oral contraceptives, antidepressants, and many other commonly used drugs can raise ALT. Depending on the patient's history and physical examination, ultrasound of the gallbladder and bile ducts, and liver scan may all be appropriate. Liver tests should be repeated again in two to three months, and if the liver abnormalities persist, the patient should be referred to a gastroenterologist for evaluation and probably liver biopsy.

Every effort must be made to determine the etiology of persistently abnormal liver tests. Testing is part of the continuing effort to prevent posttransfusion hepatitis.

Jane Straughn, M.D.

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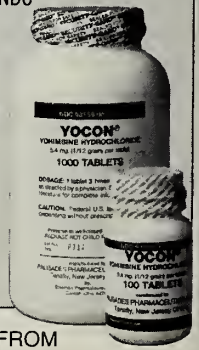

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My editorial in the Geriatrics issue (*Del Med J* 60(6):393), fudged by saying, "The American Association of Retired Persons (AARP) numbers millions in its membership." A more exact number is 28 million, giving AARP the largest membership of any U.S. association.

Bernadine Z. Paulshock, M.D.

DELAWARE PSYCHIATRY CIRCA 1988

We recently completed a survey of the use by psychiatrists of the MAO inhibitor class of antidepressants. As part of this survey, questionnaires were mailed to all psychiatrists who were members of the Delaware Psychiatric Society, the Medical Society of Delaware, or who were listed in the telephone directory. Psychiatric residents in training were excluded. Replies were received from 39 of the estimated 79 practicing psychiatrists in the state of Delaware, a response rate of approximately 50%. The responses provide the opportunity for a brief profile of Delaware psychiatric practice, circa 1988.

Of the respondents, 74% were men and 26% were women. The mean age of respondents was 52.2 years, with 18% in their 30s, 18% in their 40s, 36% in their 50s, and 28% over 60 years old. Exactly half of the practicing psychiatrists had completed residency training more than 20 years ago. Forty-four percent of respondents were trained in residencies with a psychoanalytic focus, while 56% were trained in what they described as eclectic programs. As might be expected, psychiatrists who completed residency more than 20 years ago were significantly more likely to have received psychoanalytically oriented training ($x^2 = 3.84$; p less than .05).

The private office was by far the most common practice setting among respondents (82%), followed by private hospital, and VA or state hospital. Psychiatrists were asked to describe their practice balance in terms of what type of professional activities occupied at least 25% of their work week. Outpatient psychotherapy occupied a significant share of weekly practice for 82% of respondents. This was followed, in order, by inpatient work, 46%; outpatient pharmacotherapy, 44%; diagnostic consultations, 18%; consultation-liaison work, 10%; and miscellaneous other categories such as administrative, teaching, and research, 21%. There was a trend for psychiatrists who have been in practice longer to be doing less inpatient work. Otherwise, there was no difference between older practitioners in practice characteristics than more recently trained ones.

What diagnoses do Delaware psychiatrists find themselves most frequently making? In order of frequency they were major depression, cited as one of the most frequent diagnoses by 46% of respondents; minor depression, cited by 38%; adjustment disorders, 21%; anxiety and panic disorders, 18%; and personality disorders, 10%. Two comments about diagnosis patterns: first, schizophrenia was a low frequency diagnosis for Delaware psychiatrists, which is in keeping with a national trend over the past 30 years; and secondly, the absence of alcohol and substance abuse as a common diagnosis by Delaware psychiatrists is surprising. Recent national surveys have found alcohol and substance abuse to be the most prevalent psychiatric disorder.[1]

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chiatrists used tricyclic antidepressants; 92% used benzodiazepine tranquilizers; 85%, lithium; 82%, neuroleptics; 72%, benzodiazepine hypnotics; 56% used MAO inhibitor antidepressants; 54% used non-benzodiazepine tranquilizers such as buspirone or beta-blockers; 49% used anticonvulsants; and 41% used psychostimulants.

The picture which emerges from this brief survey of Delaware psychiatry is of a specialty still largely based in private offices, and still primarily practicing psychotherapy. The past decade has seen a much-touted "biological" revolution in the diagnosis and treatment of psychiatric illness. A corollary of this shift in the *weltanschauung* has been the rise of the non-medically trained psychologist and social worker as primary therapist. Non-medical therapists are being added to the ranks of mental health professionals at a rate which is more than triple that of psychiatrists. This has caused concern in some quarters--partly over the potential for inadequate or inappropriate diagnosis and treatment, and partly over competition in an increasingly crowded therapy context.

In Delaware, though, psychotherapy still occupies by far the largest share of the daily practice of psychiatrists who were surveyed. The vast majority of respondents use medication, but a majority appear to consider use of it a minor part of their practice. Few consult for, or supervise non-medical colleagues on any substantial or regular basis. And though psychiatrists under age 45 reported receiving more eclectic training, they were no more eclectic as a group in their actual diagnostic treatment or consultative practices.

One last comment: the low rate of diagnosis of alcohol and substance abuse by Delaware psychiatrists suggests that we are perhaps not as involved as we should be in the treatment of this national epidemic. This is unfortunate, since our training and expertise should be an invaluable resource, and since a large share of alcohol and substance abusers are thought to have unrecognized underlying psychiatric illnesses which they are self-medicating with alcohol or drugs.[2-4]

Cathryn Clary, M.D.
Edward Schweizer, M.D.

Dr. Clary has a private practice in psychiatry in Delaware; Dr. Schweizer is an Assistant Professor of Psychiatry at University of Pennsylvania in Philadelphia.

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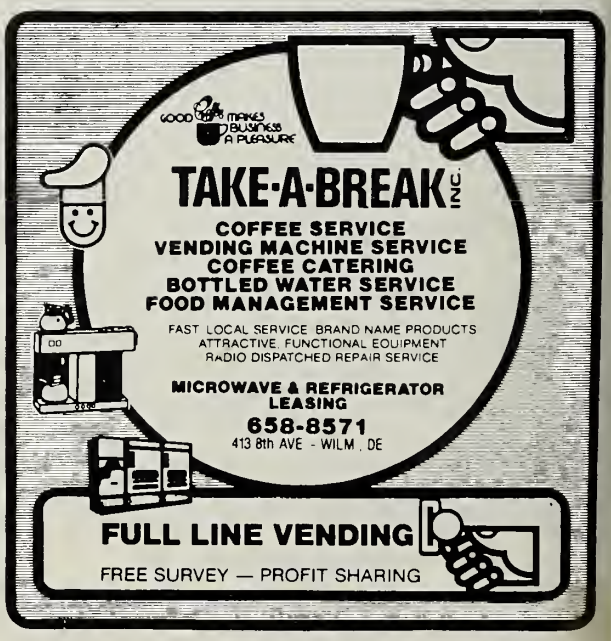

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One solution is to put Mom or Dad in a nursing home where they can receive proper care on a 24 hour basis, but at about $22,000 a year there are few families that can afford this option. Social Security and Medicare, pledged to protect people in their old age, do pitifully little to ease the burden, paying out only 6.1% of the dollars needed for nursing homes. The bulk of the money comes from families (51%) or Medicaid (41.4%). What it takes to get Medicaid is beyond the scope of this discussion, but the horrors of personal asset depletion and spousal impoverishment are real.[1]

The cost of nursing home care for today's elderly is estimated at $30-40 million. Our debt-ridden federal government says it cannot afford the bill, but nevertheless, has had unbounded funds for an SDI (Star Wars) program, on which, according to a report to be issued by the Pentagon, by 1996 the government will have spent $150 billion.

With that $150 billion, think what could be done for our elderly patients and their relatives. Enough nursing homes for all, staffed by trained, well-paid nursing help. Families no longer forced into financial and personal stress to care for an elderly relative. Parents enabled to live in an environment where they would receive proper medical care, therapy, nutrition, and mentally stimulating recreational programs. Nursing home personnel hired, trained, and given meaningful jobs with adequate salaries that pay taxes, buy homes, cars and goods, and make deposits into banks, instead of deposits into the banks of computer chips in "death ray" orbits. All this, and there would still be a huge balance left from the $150 billion the Star Wars endeavor will cost.

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hospital, or when the burden of an Alzheimer's patient is too much for your patient's family to care for at home, and you shake your head in frustration, grimace, and look up to the heavens for help, remember that we are all part of the Family of the Nuclear Age, and consider just exactly what we are doing with our money.

Edward R. Sobel, D.O.

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SHOULD PHARMACEUTICAL COMPANIES PROVIDE CME?

In one of his last speeches before he left office, President Eisenhower cautioned the country against the rising power of the "military-industrial complex." Several similar warnings have been made in recent years regarding a too close association of the educational modalities provided for prescribing physicians with the pharmaceutical industry.[1] I second and emphasize these warnings.

My concern began several years ago when the American Diabetes Association sponsored a day of nation-wide live telecasts on the appropriate management of type II, non-insulin dependent diabetes (formerly known as maturity onset diabetes, a sobriquet still true in the majority of instances). The program, which included the foremost diabetoligists in the country, was paid for by a multi-million dollar "grant" to the ADA from a company which sells one of the two second generation agents for the pharmaceutical management of this type of diabetes, the type afflicting 80% of all those with diabetes. The American Diabetes Association was the ostensible sponsor of the huge endeavor.

Recently, I received an invitation from the local chapter of the ADA to attend dinner with a speaker at one of our best hotels. Not until the dinner began were we 15 or so invitees informed that our host, in terms of financial support, was actually the Such and Such Pharmaceutical company, a major purveyor of drugs used for the treatment of diabetes. The executive director of the Diabetes Association explained that the company, which had provided a financial grant to the Diabetic Association specifically for the program, preferred to "keep a low profile," and not be acknowledged directly in the invitation to the meeting. Both the dinner and the speaker who spoke on lipid disorders in diabetics ("First principle, control the diabetes") were excellent.

But it is this policy of remaining low profile, of not requiring, and in fact, of preferring no acknowledgment for generous or total support of continuing medical education programs which is most worrisome. It seems somewhat analogous to laundering money. If there's nothing wrong with providing these conferences, then why should the support be obscured or omitted from the announcements?

One can develop expertise at recognizing programs so supported: they usually have small or no registration fees; the speakers have very good slides, often multicolored, and usually legible; and the local pharmaceutical representatives often deliver the speaker, and are present at his or her address. But few of my colleagues seem to know or care to know who's paying the speaker from whom they are learning.

I am concerned that education so supported is, if not biased, at the least preselected. Isn't it too

much to ask or expect that pharmaceutical companies responsible to their stockholders would support or provide speakers antagonistic to their own marketing efforts? The speakers, therefore, though often notable and chosen for excellence of reputation as well as speaking ability, have been winnowed so as to exclude persons with positions inimical to the mercantile positions of the sponsoring companies.

I have yet to hear a speech critically evaluating the proliferating use of second generation oral hypoglycemics, for example, or the trend away from the only inexpensive agents for the management of hypertension, or a critical discussion of drug treatment of hyperlipidemia--who would support the presentations? And as departmental budgets get smaller and more controlled by necessarily vigilant business managers, more and more of our conferences are likely to be underwritten by drug company money. In turn, and most intellectually and morally dangerous in my opinion, is the trend for the sponsoring companies to be obscured from view because their largess is in the form of grants paid directly to the department or university or society under whose aegis and rubric the programs are presented.

At our own annual meeting last year, the esteemed professor who spoke on the modern treatment of hyperlipidemia was provided by the company which makes the newest and most expensive cholesterol-lowering agent. This in itself is questionable, but the financial support was not acknowledged, nor even realized by several experts in the field who were in the audience. Does this policy carry with it any danger? Is this really a desirable or appropriate means of providing continued medical education?

Most if not almost all of the out of town speakers who come to our community now are supported by pharmaceutical monies. The speakers' probity is not questioned; but any possible biases are unknowable if their support is not announced. And the speakers' paychecks are generous. I know because I have been a recipient. I was

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never told what to say or asked in advance to see a copy of my remarks, but would it have been good business policy to support me if my remarks had been negative about the products sold by my sponsor, since there were other speakers to invite whose remarks would not have been?

cils, memo pads, and other cutesy gadgets.

Since the very first days of the "ethical" pharmaceutical companies in the United States, the provision of educational materials has been a part of their advertising.[2] So now is CME. Those who attend such events not only have the absolute right to know who is paying the speaker, directly or indirectly, but a moral obligation to ask if the information is being withheld. Conferences supported by grants, directly or indirectly, should announce such support in all their fliers.

Dr. Arnold Relman, editor of the *New England Journal of Medicine*, recently instituted a policy that all authors who have been financially rewarded in any way for the research about which they are writing or have any other fiscal interest in the paper they are submitting must tell him about it. This is an editorial policy all responsible medical journals should emulate.

How many physicians are aware that the pharmaceutical companies, good businesses to work for and in which to invest, regularly tot up the dollar costs for all advertising and related efforts such as supporting CME for each new prescription written? These figures are not shared, but must be the stuff of management meetings within the pharmaceutical companies which pay for our conferences, lunches and speakers, our pen-

Probity requires no less. All of us need to be protected against inadvertently spending the time we allot to education in listening or reading advertising material. The maxim that he who pays the piper calls the tune has never been declared inoperative.

Bernadine Z. Paulshock, M.D.

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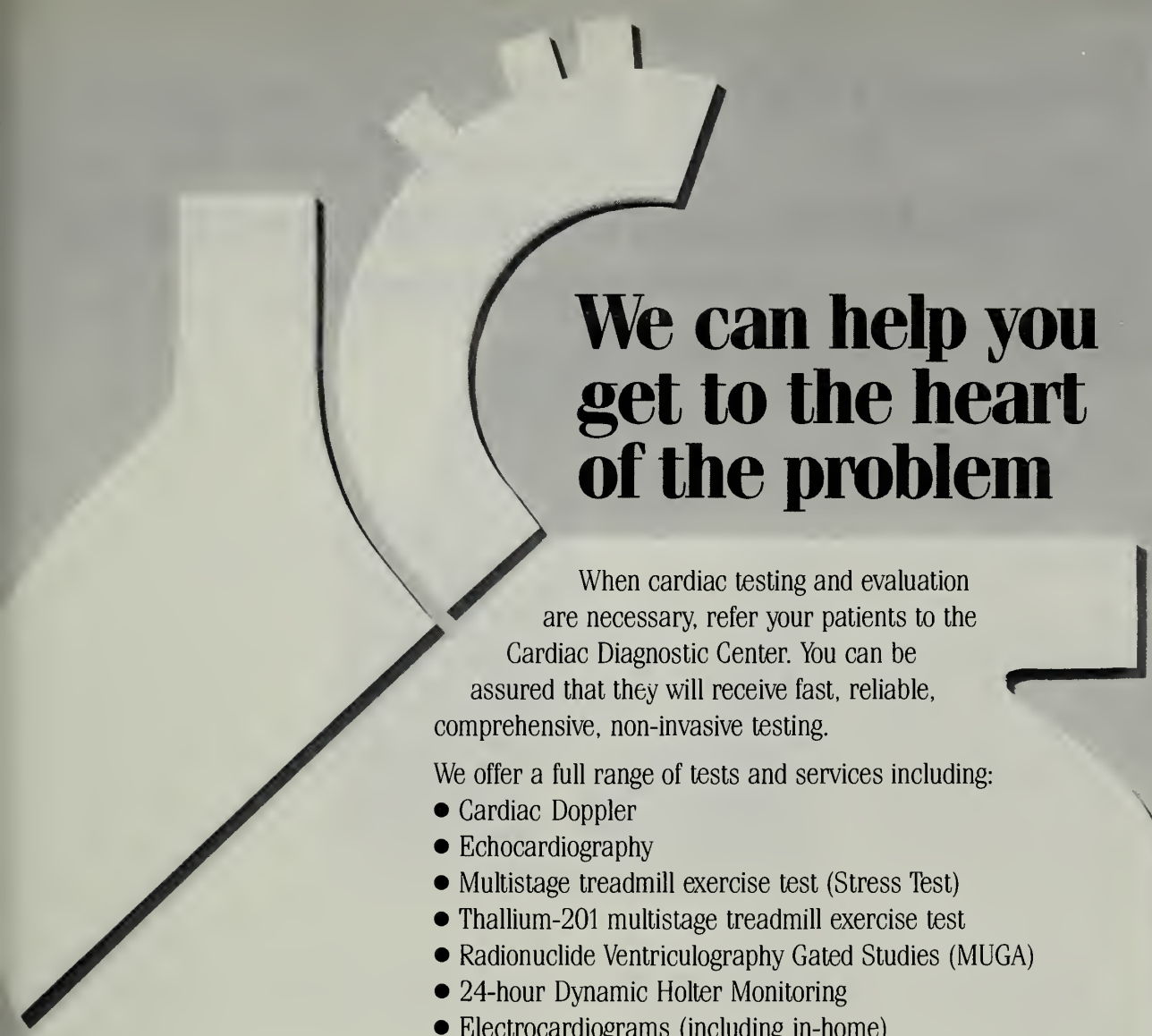

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DELEGATES' REPORT:
1988 ANNUAL MEETING OF THE AMA HOUSE OF DELEGATES

Daniel A. Alvarez, M.D.

The Annual Meeting of the AMA House of Delegates was held in Chicago, Illinois, from June 26 through June 30, 1988. The Medical Society of Delaware was represented by its president, Martin J. Cosgrove, M.D., and Delegates Daniel A. Alvarez, M.D., Peter R. Coggins, M.D., and I. Favel Chavin, M.D. The meeting was also attended by Anne Shane Bader, the Executive Director.

The AMA House of Delegates was composed of 422 seated delegates, including 336 representing state medical associations, 76 representing national medical specialty societies, and ten section and service delegates representing students, medical schools, residents, military physicians, the USPHS, and the VA. Applications for representation in the House were approved at this meeting for the American Medical Society on Alcoholism and Other Drug Dependencies and the American College of Utilization Review Physicians.

Outgoing AMA president William S. Hotchkiss, M.D., was commended by the House for his dedication and service to the AMA and to the profession. In return, Dr. Hotchkiss expressed confidence in the profession's ability to cope with and significantly influence the major changes taking place in medicine. James E. Davis, M.D., a surgeon from Durham, North Carolina, was installed as the new president of the AMA in an impressive ceremony on Wednesday evening. Delaware's president, Martin Cosgrove, was honored along with the presidents of the other state societies. Dr. Davis's inaugural address touched on numerous challenges being faced by medicine and by the country as a whole. The major focus of his address was the need for America's physicians to become more visible and more active in community affairs. He challenged all component societies of the federation to develop public service programs facilitating physician involvement in projects to improve community life. At Dr. Davis's suggestion, the AMA Board of Trustees has established a new award to be given to a state, county, or specialty society for excellence in the field of contributions for the public good.

Other AMA officers elected at the meeting included president-elect Alan R. Nelson, M.D., an internist from Utah, who is currently the Chairman of the Board of Directors. Also elected were: John H. Clowe, M.D., a family practitioner from New York as Speaker of the House, and Daniel H. Johnson, M.D., a radiologist from Louisiana as Vice-Speaker. Five regular seats and one resident seat on the Board were filled by Lonnie Bristow, M.D., California; Rufus K. Broadaway, M.D., Florida; Raymond Scalettar, M.D., Washington D.C.; Jerald R. Schenken, M.D., Nebraska; Frank B. Walker, M.D., Michigan; and Timothy E. Baldwin, resident section.

The delegates of the 1988 Annual Meeting considered numerous reports and resolutions. It is not the intent of this report to detail every item of business, but to summarize the major issues and to mention any business that might be of special interest to the Medical Society of Delaware.

In regard to AMA finances, it was reported that in fiscal year 1987, total revenues were

$150,648,000, and total expenses were $144,608,000. In spite of prudent management, expenses were up 8.5% over 1986. Therefore, after some debate the House approved an increase in dues of $25.00 for 1989. Medical student and resident dues are to remain unchanged, other categories are to be increased proportionately to regular dues, and unified societies will continue to receive a 10% rebate. As a recently unified society, the Medical Society of Delaware will continue to receive a percentage of state and county revenues loss through its first five years of unification.

The House approved several reports and resolutions addressing the AIDS issue. In addition to reaffirming previous AMA policy, the House adopted new policy including encouraging states to implement tracing programs similar to those used for other communicable diseases, always keeping in mind the need for confidentiality as well as appropriate counseling. The House also approved policy that would recommend that HIV positive mothers refrain from breast feeding and that all human milk bank donors should have HIV testing, and milk from positive donors should not be used. Mandatory testing of prison inmates remained a controversial subject, and the House expects a report on this subject at the Interim Meeting.

A comprehensive report from the Board of Trustees was a major initiative on drug abuse in the United States. The report included the recommendation that the current focus on stopping the sale of illegal drugs be redirected to curbing demand through education and treatment. It is recommended that better coordination of federal efforts might result if a position is made for a high ranking official in the Executive Branch to assume responsibility for the effort against drug abuse. Among the initiatives supported by the Board were an expansion of treatment and rehabilitation programs, a nationally coordinated education program that complements local efforts, and the expansion of community based youth prevention programs.

As usual, the Medicare program received much attention from the delegates. A number of resolutions were considered regarding the problems physicians continue to have with the MAAC provisions. Policy adopted by the House included starting another appeal to Congress to repeal MAACs, supporting federal legislation which would rectify Medicare contractual inequities, and establishing the principle of freedom to continue to oppose the concept of "participating and non-participating" physicians and to work out ways to enable the physician to treat Medicare patients outside of the regulatory constraints imposed by the Medicare program.

The provision of the Medicare program that received the most attention from angry delegates was Medicare's "medically unnecessary" denials. The House of Delegates instructed the AMA to seek repeal of this provision and, in the meantime, to press HCFA and carriers to make changes to current procedures which cause the most problems. Among the changes the delegates requested are rewording of patient notification and patient waiver forms so that it does not appear that the physician is rendering poor care; requiring that denials be reviewed by physicians and surgeons, assuring that notification include clear identification of the service being denied; and requiring carriers to expedite physician requests for reconsiderations and appeals.

The Supreme Court in Patrick v. Burget regarding peer review prompted a comprehensive report addressing the legal liability concerns for physicians who participate in peer review. The report concluded that risks are minimal if the review is conducted in good faith and with proper procedure. The report also stated that additional protection from antitrust suits should be developed. The House also reaffirmed that physicians who experience adverse peer review should have redress, but treble damages are inappropriate.

No AMA meeting would be complete without its issue of greatest controversy. The 1988 meeting was no exception. The AMA Board of Trustees submitted a report proposing a pilot program to create a Registered Care Technologist (RCT) in response to the nursing shortage. The RCT is described as a bedside care giver who executes the orders of a physician at the direction of the head nurse at the bedside. The report received much attention from the media and several nursing organizations were allowed to speak in opposition to the proposal during the meeting. Many delegates were opposed to the proposal primarily because of the animosity it seems to engender among nurses. Dr. Alvarez, with the concurrence of the entire Delaware delegation, spoke in opposition to the proposal. Delaware's opposition focused on three points: the

AMA appeared to be meddling in the basic structure of another profession; the AMA proposal was initiated without the input of nursing organizations; and the proposal was bound to create a rift between the physician and the nurse. Those who supported the proposal reminded the House that many overtures had been made by the AMA to nurse organizations for a joint effort to solve the nurse shortage, but all attempts had been turned down. They cited the predictions that there will soon be a major crisis in the delivery of health care if something is not done to solve the shortage. After much discussion, the House amended the report to require certification and registration of the RCT rather than licensure, and then referred the report to the Board of Trustees.

Among the many other issues addressed at the AMA Annual Meeting were long term health care, relative value scale, professional liability, office-based laboratory testing, and expansion of no smoking policies. Unfortunately, it is impossible to detail every matter of business in this brief report. For those interested, refer to the first two July issues of the *American Medical News* for more detailed reports. In addition, any delegate will be happy to respond to questions that you may have about the proceedings of the 1988 Annual Meeting.

It should be noted that the Medical Society of Delaware's new status as a three delegate society received much notice by other delegations. Moreover, many delegates commented that our organization must have something very special to have made such a smooth transition into unification.

Dr. Alvarez represented the Medical Society of Delaware at the Southeastern Delegation Executive Meetings. At the invitation of the Speaker of the House, he also served as a member of Reference Committee D, which heard testimony on most hospital medical staff related issues.

As stated in previous reports, all members of the AMA are welcome to attend AMA House of Delegate meetings and any member may testify at the Reference Committee meetings. If a member of the Medical Society of Delaware cannot attend and wishes to have his or her opinion known, he or she is encouraged to discuss the subject with one of the delegates. The next meeting is the Interim Meeting scheduled for December.

Dr. Alvarez is Chairman of the Medical Society of Delaware Delegation to the AMA.

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Deaths

ELTON RESNICK, M.D.

Dr. Elton Resnick, a family practitioner in Wilmington for 33 years died August 27, 1988 in the Miami Heart Institute in Florida. He was 76. He lived in Florida since his retirement in 1972.

Dr. Resnick graduated from the University of Maryland Medical School in 1937 and came to Wilmington in 1939. He served in the Army Medical Corps from 1942 to 1946, in both the European and Pacific theaters, and received a letter of commendation while serving in Italy with the 5th Army.

He was director of Family Practice at the old General Hospital, as associate of the hospital's department of Medicine, and a member of the board of the Visiting Nurse Association. He served several terms in the 1950s as president of the state chapter of the Academy of General Practice, Wilmington. He was also a past president of the Academy of Family Practice. Dr. Resnick was a member of the American Medical Association, the Medical Society of Delaware, and New Castle County Medical Society.

ERVIN L. STAMBAUGH, M.D.

Dr. Ervin L. Stambaugh, a Sussex family practitioner and general surgeon for more than 50 years, died at his home September 20, 1988. He was 86.

Dr. Stambaugh graduated from Penn State University in 1924 and Jefferson Medical College in 1927. He served a two year residency at Jefferson Hospital. In 1929, Dr. Stambaugh moved to Lewes, and was appointed a U.S. Public Health Officer, a post he held for 50 years. He also worked at the Beebe Clinic and taught nurses at Beebe Hospital.

During World War II, Dr. Stambaugh often traveled to ships at sea to treat injured soldiers and sailors.

Dr. Stambaugh started a private practice in 1950, with offices in both Lewes and Rehoboth Beach, finally retiring in 1981. In 1974, he was given an outstanding service award by Governor Sherman Tribbitt for his work in treating alcoholism.

He was a past president of the Medical Society of Delaware, and a member of the Sussex County Medical Society, the American Medical Association, and the American College of Surgeons, as well as the Phi Omega Sigma fraternity and the Lambda Omega Lambda academic honor society at Jefferson Medical College.

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Letters To The Editor

TAKING THE MALPRACTICE CRISIS INTO PHYSICIAN HANDS

To the Editor:

In the May 1988 issue of *Delaware Medical Journal*, Mr. Battaglia, legal counsel for the Medical Society of Delaware, outlined an arbitration proposal which could dramatically improve the medical malpractice litigation climate in the state of Delaware. The proposal is almost too good to be true, but it is true.

With the approval of their malpractice carriers (PHICO has already done so), Delaware physicians can literally take the malpractice insurance crisis into their own hands by entering into an arbitration agreement with each of their patients. Such an agreement will allow the physician or the patient to settle any disputes which may develop between them (including claims of malpractice) by arbitration.

So what is so great about arbitration? Compared to jury trial, arbitration is cheap, quick, and less damaging to the physician and the patient alike. Arbitration is less expensive because there is less posturing, and hence, there is less preparation needed than for a jury trial. Arbitration is quicker because there are fixed time frames in which it must take place. Also, arbitration can be scheduled without having to wait to get on over-burdened court calendars. Arbitration is less damaging because it is a less adversarial process. For example, arbitration hearings are not public, so there is less chance of the process damaging a physician's professional reputation. With less posturing, disputes can be resolved without the patient and the physician becoming bitter rivals.

Where voluntary, binding arbitration has been tried, it has been readily accepted by patients, it has reduced the amount of awards, and it has shortened the time for resolution of complaints. In addition, since the arbitration process is less expensive for patients as well as physicians, more patient's attorneys can afford to accept smaller cases and thus, more patients can potentially be benefited through arbitration than through the jury system. Finally, an added advantage to this proposal is that the three arbitrators selected (one by the patient, one by the physician, and one by the other two arbitrators), are not required to be lawyers, and so are more likely to be knowledgeable in medico-legal matters than are 12 lay jurors. Hence, an additional element of fairness is added to the process of resolving malpractice disputes.

In all respects, I believe Mr. Battaglia's proposal has provided the physicians of Delaware with an excellent way to take a first giant step toward controlling the medical malpractice litigation crisis in our state.

Stephen Permut, M.D., J.D.

DIAGNOSIS OF THORACIC OUTLET SYNDROME

To the Editor:

In the June, 1988 issue (*Del Med Jrl* 60:307-310), Dr. Allen Davies reported a large series of patients carrying the diagnostic label of thoracic outlet syndrome (TOS). His article displays the enthusiasm and therapeutic zeal for a diagnosis which many neurologists feel is quite rare.

Thoracic outlet syndrome is frequently diagnosed by physicians and indeed, also by lawyers who concern themselves with accident victims. Explosive growth has therefore occurred in medico-legal aspects of this entity, as has confusion attending its diagnosis. Increasingly, and often on specious grounds, the diagnosis is set forth to a jury. Just as frequently, no firm criteria exist for such a diagnosis. Subsequent review of such cases suggests that in the absence of firm diagnostic standards, on many occasions alternative diagnoses explain the symptoms of a hypothetical TOS. Only a small residuum of patients will ultimately be so diagnostically labeled. Careful scrutiny of Dr. Davies's paper is therefore important both from diagnostic and medico-legal viewpoints.

The Adson sign is seen in normal people. In those diagnosed as having unilateral TOS, I have not infrequently noted an Adson sign on the uninvolved side. It certainly is a phenomenon, but only semantically is it a sign and even then not a pathognomonic one. When associated with pain in an apparent radicular or nerve distribution, a latent carpal tunnel syndrome, ulnar entrapment at wrist or elbow can be responsible. Since the sign so frequently occurs in asymptomatic patients, its presence is of doubtful value.

The point may also be made that vascular compression alone does not connote compression of those nerves in relationship to the vessels. A vasospastic syndrome may exist at times and may respond to nifedipine. It seems to be worsened by the often associated reflex myalgia one encounters which itself may be augmented by increased coffee, cigarettes, and psychic strain associated with the sequence of events. This myalgia and spasm is frequently noted even when no evidence of discogenic or radicular dys-

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function is detectable. A proportion of cases are referrable to a traumatically acquired temporomandibular syndrome, and this merits exclusion. Reflex dystrophy may also at times be confused with TOS.

Many electrophysiologists, including Bannister from Queens Square, have expressed great doubt about the diagnostic value of EMG. Even advanced techniques such as inserting a stimulating electrode adjacent to the C7-8 roots have proven unsatisfactory. Somatosensory evoked potential studies have a somewhat increased diagnostic yield. Therefore, it is not purely a matter of what the EMG indicates, but also a matter of having such studies performed by electromyographers of acceptable caliber, training, and qualification.

Within the last month I had occasion to review two operated cases of TOS, treated via the operation described by Dr. Davies. One patient was unchanged, and one was worse. In each patient the EMG played a great diagnostic role. Yet in each instance the EMG lacked sensory studies or delayed F wave responses and was thus inadequate or misleading. When a controversial procedure is performed on the basis of an improperly performed study, diagnostic errors are unacceptably high.

Given explosive growth in the accident industry, coupled with the tortured logic so beloved by the judiciary, it would be unfortunate if Dr. Davies's presentation legitimizes as frequent such an uncommon and controversial diagnosis.

Thoracic outlet syndrome does of course, exist, but if one employs the criteria of hypothenar atrophy, C8 sensory dysfunction, positionally related symptoms, and accurately performed state-of-the-art electrical studies, it is actually rare.

Resections of the first rib, based purely on neurogenic symptoms, are frequently foredoomed to failure. Surgery may be more strongly indicated for certain extrinsic vascular compression.

Barry E. White, M.D.

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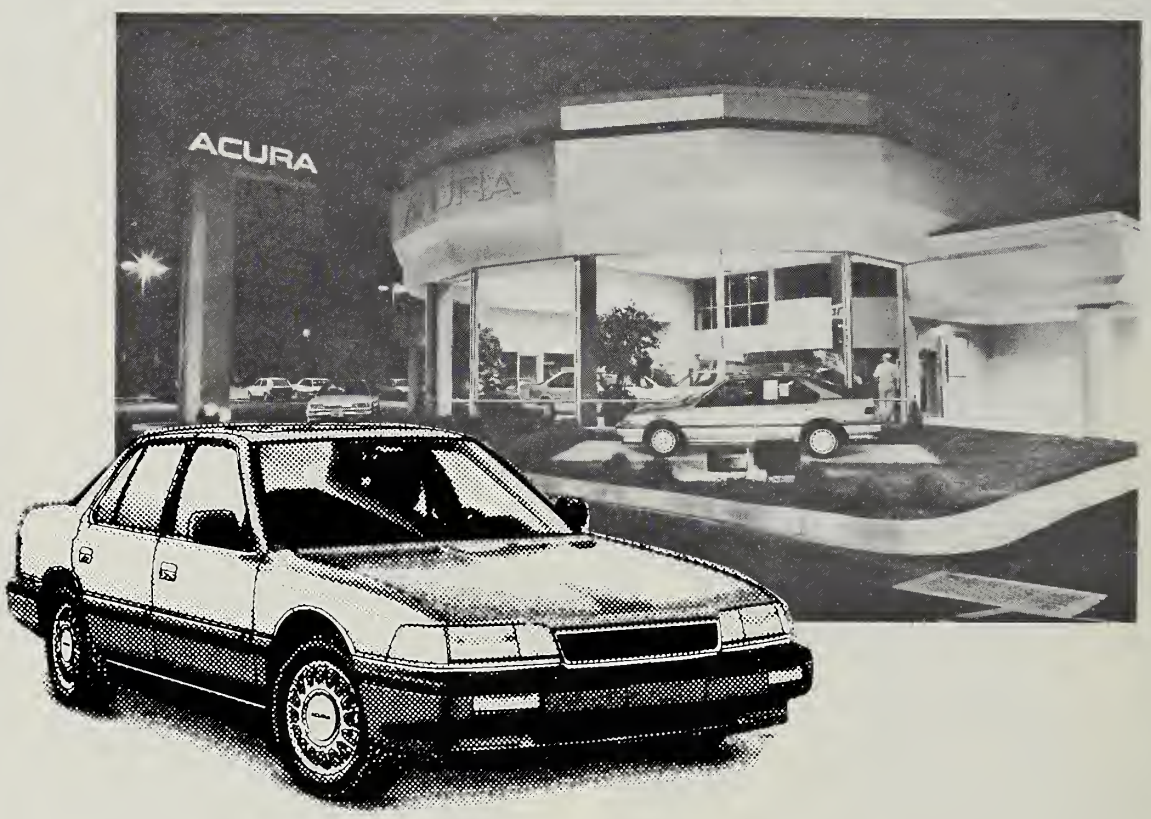

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Book Reviews

William L. Jaffee, M.D., Book Review Editor

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CLINIMETRICS, by **Alvan R. Feinstein, M.D.** 1987; New Haven, Connecticut: Yale University Press. 272 pp. Price $25.00.

This is a book about clinical decision making in medicine. The author has studied many aspects of clinical judgment and methods for the last 20 years and is superbly qualified to comment on the subject.

The concept of clinimetrics was first described in 1983 in the *Annals of Internal Medicine* by Dr. Feinstein as "...an intellectual domain concerned with the process of measuration that converts basic clinical phenomena into basic scientific data." Further, "the main requirement for scientific quality in data is a consistent, reproducible process of observation and expression. This requirement can be attained with appropriate attention to basic descriptive activities and to the operational criteria that convert raw descriptions into the variables, categories, and composite aggregates of suitably chosen scales."

The book describes the process whereby the physician categorizes discrete data points and clinical impressions into indexes which then allow simplified comparison of the patient's circumstances to that of statistical groups. For example, when a patient is described as being in mild congestive heart failure based on the observation that he has 2+ pitting edema, bibasilar rales 1/3 of the way up, a prominent s3, and is in moderate distress, five clinimetric indexes have been employed. Four describe the intensity or degree of a sign or symptom, and one describes the degree of the diagnostic entity. Problems arise because there are often dozens of conflicting indexes in use which apply to the same information; comparison to data in the literature is often one of apples and oranges.

Dr. Feinstein notes that rarely is there a scientific or statistical basis for a clinical index, and they are often adapted from laboratory research and inappropriately applied to clinical work. Unlike laboratory data, which is collected and reported under strict guidelines so as to insure reliability, consistency and reproducibility, with known variability, no such quality control mechanism currently exists for clinical data.

According to Dr. Feinstein, physicians constant-

ly use clinimetric indexes during their practice of medicine. His goal is to deliberately examine this process and develop formal methods of creating and standardizing indexes to minimize confusion and maximize the benefits for both academic and clinical medicine. In particular, he notes that most clinical data is not entered into computer data bases because of its unwieldy nature, and he views the development of standard indexes as a prerequisite to using this data in expert systems.

Clinimetrics presents the reader with a problem of vast proportions. It teaches us that thousands of times each day physicians use hundreds of clinimetric indexes, and currently do so in a haphazard, partially productive way. Dr. Feinstein proposes an elaborate solution; the implementation will likely take place in some form, and will be of great benefit to medicine.

This book is must reading for those who intend to have a hand in the shaping of medicine in the 21st century.

Brian M. Willard

Mr. Willard is a third year medical student at Jefferson Medical College.

HEMATOLOGY: THE BLOSSOMING OF A SCIENCE, by **Maxwell M. Wintrobe, M.D., Ph.D.** 1985; Philadelphia: Lea and Febiger. 563 pp. Price $60.00.

Maxwell Wintrobe is one of the gurus of hematology. He was in his 80s when he wrote this book. His career, which spanned from 1925 when he graduated from University of Manitoba Medical School to the present, covers the period from the pale beginning of hematology through its golden age. This is both an autobiography and a story of all the pioneers of hematology.

By chance when he was a young assistant in medicine at Tulane University, in 1926, Dr. Wintrobe was asked by his chief to help in, then take over, the writing of the hematology section in *Tice's Looseleaf Practice of Medicine.* He did this repeatedly and his research for it gave him the background to write in 1942 his *Textbook of Hematology*, which became the standard text, having gone through eight editions.

In 1943, when he was an assistant in medicine at Johns Hopkins, he was invited to chair the Department of Medicine at University of Utah. He has worked there to the present and made it

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Dr. Wintrobe's 60-plus year career has spanned the time from the beginnings of hematology when pernicious anemia was a uniformly fatal disease and iron deficiency was not recognized, to the present era of intertwining hematology with molecular biology, human genetics, and chemotherapy.

He tells the story of hematology by describing the careers and contributions of its researchers. He includes many personal details and interrelationships, and describes how their goals were met.

The book ends with: "This monograph is dedicated to the young and to the dreamers--there is much more to discover."

David Platt, M.D.

SYSTEMIC LUPUS ERYTHEMATOSUS, edited by **Robert G. Lahita, M.D., Ph.D.** 1987; New York: Wiley Medical Publications. Price $95.00.

I have recently reviewed the current edition of *DuBois' Lupus Erythematosus*, a classic rheumatology textbook. Now, Dr. Lahita has edited another even more extensive textbook with many fine contributors reviewing the current experimental and clinical tenets of this fascinating illness. The text is all-inclusive, dealing with basic and clinical aspects of the disease. The references are extensive and are as recent as 1985. The rapid evolution of knowledge about lupus has already rendered some chapters dated. Regardless, Dr. Lahita's text adds considerably to the existing literature.

James H. Newman, M.D.

CLINICAL CONCEPTS IN REGIONAL MUSCULOSKELETAL ILLNESS, edited by **Norton M. Hadler, M.D.** 1987; New York: Grune & Stratton. 370 pp. Price unavailable.

This is the second edition of Dr. Hadler's textbook on regional musculoskeletal disorders. The original text was called *Medical Management of the Regional Musculoskeletal Disorders.* The current text is not so much an update of the original as a follow-up, in which the editor and contributing authors primarily formulate an understanding of evaluating patients' complaints of regional musculoskeletal pain and disability, and secondly formulate an understanding of appropriate

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evaluation and management of these complaints. All the comments made in this text are evaluated in light of the effect of musculoskeletal complaints on society particularly as it relates to work disability, workmen's compensation, and government intervention. This latter aspect of the book is a favorite topic of Dr. Hadler, and one in which he has many well defined viewpoints.

Anyone who has ever read Dr. Hadler finds him to be interesting, controversial, thought provoking, and rather hardnosed in his views. I still find it a positive book and recommend it.

James H. Newman, M.D.

OVERCOMING BREAST CANCER, by **Genell Subak-Sharpe.** 1987; Garden City, New York: Doubleday & Company, Inc. 181 pp. Price $16.50.

The latest American Cancer Society statistics state that one of every 11 women will develop breast cancer. For this reason, it is crucial that all women are educated and become knowledgeable about early detection, self-exams, and warning signs. This book aspires to achieve that goal and presents everything laymen need to know about breast cancer in a simple yet straightforward fashion.

The author manages to condense a vast amount of information into this slim text. Included are current statistics on breast cancer, risk factors, warning signs, practical instruction, and clear illustrations on breast self-examination. Guidance on options for surgery, chemotherapy, and radiation are also presented. The impact on the patient's family is also examined.

The information is well organized. Large topic headings make subject matter available for immediate reference. Stories of actual patients are presented and provide a personal dimension to information that might otherwise be too dry for the lay reader. A helpful glossary and listing of volunteer and support groups appears at the end.

Information in the book is discussed objectively; the author never commits herself when introducing multiple options for surgery and treatment. At times, I wish she would have taken a stand. However, her impartial attitude allows readers to make their own decisions.

The title seems inappropriate because it implies that it is for cancer patients only. This publication is for *all* women and I strongly recommend it. Being a woman is risk enough for breast cancer. Stressing the importance of early detection to our patients is critical.

Tammi D. Davis, M.D.

Dr. Davis is a third year resident in Family Practice at the Medical Center of Delaware.

RHYTHM QUIZLETS - SELF ASSESSMENT, by **Henry J.L. Marriott.** 1987; Philadelphia: Lea & Febiger. 189 pp. Price $16.50.

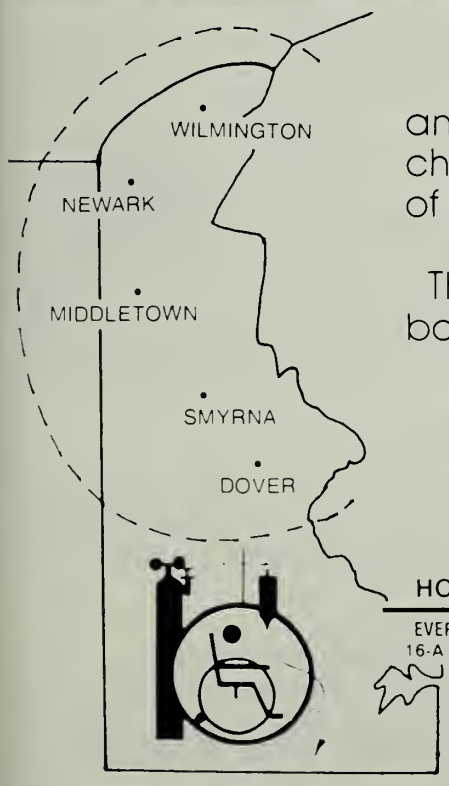
Arrythmophiles and all physicians using electrocardiograms should enjoy this simple, instructive, and intriguing book. If you enjoy crossword puzzles as a relaxing way to pass time, you will be pleased with this manual. In general, noncardiologists will have their memories jolted by this quick review of facts studied in the distant past, and they should be pleased to realize they can be brought up to date with only a little effort. However, this manual has special value to those working in intensive care units and operating rooms, where honing diagnostic and therapeutic skills is important for those who must act quickly in emergency situations.

Unknown tracings are presented on the left hand page with interpretations on the right. The thrust of the text is diagnosis, with occasional notes on treatment. Emphasis is on basic interpretation with special points concerning the rationale of diagnosis and the mechanisms of the arrythemia. Diagnoses are confined to arrythmias and conduction defects. Additional nonarrythmic diagnoses, such as chamber hypertrophy and myocardial infarction are commented upon when they are obvious.

The book is divided into three zones--green, yellow, and red. The green zone presents straightforward disturbances of rhythm, suitable for the beginner. The degree of complexity of the disturbances increases through the yellow zone and into the most intricate disturbances in the red zone.

I heartily recommend this succinct manual to all physicians using electrocardiograms in their medical practice.

James M. Hofford, M.D.



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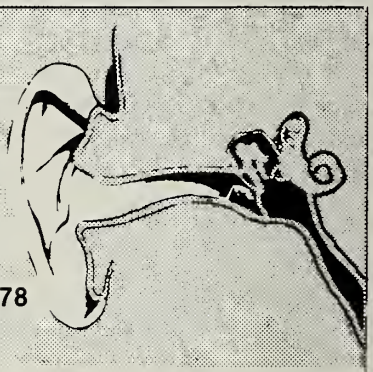

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In Brief

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CLINICAL MEETING AND NOTICES

AMERICAN CANCER SOCIETY NATIONAL CONFERENCE

The American Cancer Society will hold a National Conference on Advances in Cancer Management December 7-9, 1988 at the Hyatt Regency Hotel in Los Angeles, California. The objective of the conference is to increase health professionals' knowledge about advances in cancer management. The conference is accredited for 16 hours of Category I credit. For more information, write to the American Cancer Society, National Conference on Advances in Cancer Management, 3340 Peachtree Road, NE, Atlanta, Georgia, 30026.

199th ANNUAL MEETING OF MEDICAL SOCIETY OF DELAWARE

The 199th Annual Meeting of the Medical Society of Delaware will be held November 18 and 19, 1988. On Friday, November 18 at the Delaware Academy of Medicine Building in Wilmington, Reference Committees will meet at 10:00 a.m., and the House of Delegates will convene at 1:30 p.m. The Scientific Session will be held on Saturday, November 19 at the Hotel duPont in Wilmington starting at 8:30 a.m. For more information, call the Medical Society of Delaware at 658-7596 or downstate at 800-348-6800.

SOUTH CAROLINA ACADEMY OF FAMILY PHYSICIANS

The 40th Annual Scientific Assembly of the South Carolina Academy of Family Physicians will be held at the Inter-Continental Hotel on Hilton Head Island, South Carolina. The program is accredited for 19.25 hours of Category I credit. For more information, contact Mrs. Margaret A. Turner, Executive Director, South Carolina Academy of Family Physicians, PO Box 771, Mauldin, South Carolina, 29662, or call 803-288-6647.

BEHAVIORAL AND DEVELOPMENTAL PEDIATRICS

North Shore University Hospital and Albert Einstein College of Medicine/Montefiore Medical Center are joint sponsors of a program concerning The Practice of Behavioral Pediatrics in Children and Adolescents, to be held January 30-February 9, 1989, at the Plaza Cancun and Villas in Cancun, Mexico. Designed for primary care physicians, participants will be eligible to receive 23 credit hours in Category I from the AMA. For more information, contact Ms. Robin Harvey, Shield International Meetings, 1560 Broadway, Suite 1308, New York, New York, 10036, or call 800-221-4876.

FIRST NATIONAL CHOLESTEROL CONFERENCE

The first National Cholesterol Conference will be held on November 9-11, 1988, at the Hyatt Regency Crystal City in Arlington, Virginia, to meet the increasing need for the latest scientific and programmatic information about cholesterol. The conference will provide a unique forum for researchers and physicians to share new knowledge and program successes in this rapidly changing field. Continuing Medical Education credits have been applied for. For more information, call the Cholesterol Conference headquarters at 301-951-3275.

HEALTH CAREER DAY

The Delaware Business/Industry/Education Alliance is sponsoring the first annual Health Career Day on November 16, 1988, at the Stanton campus of the Delaware Technical and Community College. This event seeks to stimulate interest in health care as a career among local high school students. For more information, contact Jane DelSordo, Director of Volunteers, St. Francis Hospital, at 421-4104.

STATEMENT OF OWNERSHIP, MANAGEMENT AND CIRCULATION

(Act of August 12, 1970; Section 3685, Title 39, United States Code) DELAWARE MEDICAL JOURNAL published monthly at 1925 Lovering Avenue, Wilmington, Delaware 19806.

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The purpose, function, and nonprofit status of this organization and the exempt status for Federal income tax purposes have not changed during preceding 12 months.

Extent and Nature of Circulation	Average number copies each issue during preceding 12 months	Actual number copies of single issue published nearest to filing date
A. Total Number of Copies Printed.....	1621	1582
B. Paid Circulation		
1. Sales through dealers and carriers, street vendors, and counter sales.....	154	115
2. Mail Subscriptions.....	1340	1361
C. Total Paid Circulation.....	1494	1476
D. Free distribution by mail, carrier, or other means samples, complimentary, and other free copies.....	31	20
E. Total Distribution.....	1525	1496
F. Copies Not Distributed		
1. Office use, left-over, unaccounted, spoiled after printing.....	96	86
G. Total.....	1621	1582

I certify that the statements made by me above are correct and complete.

ANNE SHANE BADER
Business Manager

President's Page

REPORT OF THE PRESIDENT

One year has passed since my succession to the Presidency of the Medical Society of Delaware. During this year, I have had the opportunity to meet the privilege and responsibility of representing you and this Society with the political leaders of our State and the legal, judicial and business hierarchy of Delaware. I have traveled to Medical Society meetings in neighboring states and to national medical forums to listen, to learn and to represent the Medical Society of Delaware. I believe this has given me a unique perspective, perhaps honed by the time spent in the traveling of 42 round trips from Seaford to Wilmington and 17 round trips from Seaford to Dover on Medical Society business in the course of this past year. I will share this perspective with you.

Threats to private medical practice and quality medical care for our patients are indeed formidable. But we are members of a great and noble and caring profession at a most exciting and challenging time. We are practicing our profession of medicine in a place, the State of Delaware, in which there remains much of the good will and trust of the traditional doctor/patient relationship. It is also a state with leaders who are generally responsive to the concerns of their citizens—both patients and physicians—who are genuinely interested in solutions to the obstacles to quality health care and not in demagogic posturing or blame-fixing. We are thus doubly blessed as Delaware physicians. We are also, however, doubly obligated. We must continue to strive to be better, more caring physicians, and more involved citizens. We must accept our responsibility as the advocates of quality health care, healthy lifestyles and healthy environment for our patients. We must be as concerned with toxic wastes, seat belt legislation, and ground water pollution as about Medicare fee freezes and malpractice liability problems. We also must become more involved in the political process. We must speak out on health care issues individually to our patients and through organized medicine and our political action committees at the county, state and national levels.

The challenge of the tragic malady of AIDS was met on many levels by the Medical Society of Delaware. A Blue Ribbon AIDS Commission chaired by Judge Robert C. O'Hara and consisting of a broad-based group of concerned and involved Delawareans was created by the Medical Society of Delaware. This group considered many of the complex legal, medical, educational, and ethical issues of the AIDS epidemic. Many of the recommendations of the AIDS commission, including the Pennsylvania Medical Society policy on AIDS, were adopted by the Board of Trustees of the Medical Society of Delaware. The efforts of Lee Buckler, M.D., in the sometimes difficult deliberations of this body are to be particularly commended.

Education and the eradication of misinformation about AIDS is of paramount importance. Representatives of the Blue Ribbon AIDS Commission of the Medical Society met with Governor Castle and with the joint finance committee of the state legislature to urge increased funding for AIDS education.

Simultaneously, the Medical Society of Delaware, the Bar Association, and the Delaware Dental Society came together in planning and presenting a day-long educational "Professional

Conference on AIDS," drawing top-flight experts from all the professions, in April at the University of Delaware. Dr. John Hogan and Dr. Peter Coggins contributed prominently to this successful effort. This commendable spirit of cooperation between our professions has also resulted in a joint journal publication of the valuable material presented in the AIDS conference. This unique collaborative effort of our professions will be followed by a further joint project on drug dependency and substance abuse.

The need for current and accurate information on this evolving epidemic for our educators and ultimately our children was recognized. The Physicians' Speakers Bureau on AIDS was instituted by the Board of Trustees and offered to the school districts throughout the State of Delaware. Medical Society resources were allocated for audiovisual equipment to support this program. A total of 34 physicians participated in an all day educational session with 1,500 Brandywine school district staff and employees on August 31, 1988. The program was extremely well received. Unfortunately, to date this is the only school district to utilize this program. It is hoped that other school districts will utilize this Medical Society educational resoure, splendidly led by Dr. Diana Dickson-Witmer.

The Insurance Evaluation Subcommittee of the Liability Insurance Committee of the Medical Society of Delaware has been extremely active throughout this past year to investigate and maintain continued viable malpractice insurance for the physicians of this state. We have considered the possibilities of a risk retention insurance group for the physicians of this state. The development of a captive insurance company between the Medical Society of Delaware and a prominent local insurance group was also evaluated. Difficulties with these approaches were encountered because of the relatively limited number of physicians in this state and also because of difficulty with reinsurance. A possible association with captive physician-owned insurance companies in neighboring or more remote states was also explored. Numerous discussions with PHICO, our endorsed carrier, have continued and as of November 1, the details regarding PHICO's new rates are yet to be resolved. The committee was also involved with lengthy discussions with CNA, a new carrier to this state. At the present time CNA malpractice insurance is available in Delaware and is co-endorsed by the Medical Society. Stable malpractice insurance is available for physicians of this state. This Society, however, is committed to continue to explore and investigate all malpractice insurance alternatives.

An alternative to resolve doctor/patient disputes outside the malpractice court system has been introduced into Delaware. At my request Mr. Victor Battaglia, our attorney, has drafted a proposal to utilize the arbitration process. This draft proposal appeared in the May 1988 issue of the *Delaware Medical Journal.* At this time, a pilot program involving physicians of three selected medical specialties is being developed. It should be noted that arbitration should not be considered unless a physician has the agreement of his professional liability insurance company.

Legislative activity in this past year has again required much vigilance and involvement by Medical Society members and by Mr. Ned Davis, our legislative specialist.

Legislation allowing nonphysician incursion into medical practice in the form of the optometric and physical therapy bills was opposed by the Society. These bills did not reach the legislative floor for voting. These efforts, however, will not cease.

Senate Bill 469, introduced by the Medical Society, to require an affidavit from a qualified medical expert prior to filing a medical malpractice suit, easily passed the Senate but did not come before the House. I believe the very negative *News-Journal* editorial was the prime factor in the demise of this worthwhile legislation. We fully intend to seek to reintroduce this bill in the next session of the legislature.

Senate Bill 475, bringing hospital, medical society, and other peer review action in Delaware under protection of the Health Care Quality Improvement Act of 1986, became law in Delaware this year. This bill, caused to be introduced by the Medical Society of Delaware, affords protection from antitrust suit in conscientious peer review. All of you, as members of the Society, were able to participate directly by mail ballot in determining the future direction of peer review in Delaware. Prompt and rapid action was necessitated by the somewhat unexpected adverse *Patrick* decision by the United State Supreme Court. We were all well prepared to make a reasoned decision by the prior timely in-depth discussion

which appeared in the *Delaware Medical Journal* regarding the legal ramifications of peer review by our eminent Society attorney, Mr. Victor Battaglia. I was very impressed and gratified at how quickly and how well the various elements of the Medical Society of Delaware and the State of Delaware worked together. As a result, the State of Delaware was the first state to be placed under the Health Care Quality Improvement Act following the adverse Supreme Court "Patrick Decision."

Our experiences with the State Legislature have lead to the formation of a legislative action committee, chaired by Dr. Steve Permut. This group, working with Ned Davis, will maintain a daily presence in Dover during committee and legislative sessions. It will endeavor to act as a general health and medical information resource to our legislators. I urge physicicans from every specialty to come together in the presentation of a united agenda to our legislators. Special interest and splinter lobbying efforts within the medical community are divisive and can be counterproductive. In Delaware, let us have a House of Medicine that is not divided.

We have completed two years experience as a unified state medical society. We have regained any temporary loss of membership numbers initially encountered and I believe Medical Society of Delaware membership is at an all time high. I also believe that we are now a more cohesive and pro-active society. The future of this Society and of medicine in general rests in our young physicians. To this end I have welcomed all physicians-in-training who are AMA members in Delaware to become members of the state and county medical societies. Furthermore, I have caused a resolution to be introduced for your consideration in the House of Delegates to amend the Bylaws of this Society to add a seat on the Board of Trustees of the Medical Society for a full voting physician-in-training member. Our young physician-in-training are now acquiring skills and attitudes with which they will practice medicine throughout their professional lives. It is now time to involve these physicians in the process of organized medicine.

My work and the business of this Society could not have been accomplished without the participation, energy and activity of your Board of Trustees and of the numerous standing and special committees of this Society. To all of these physicians of good will and intellect, I am grateful.

I wish to especially acknowledge our Executive Director, Anne Shane Bader. Her tireless devotion to duty and her high standards of past performance have in great measure enabled this Sussex County physician, with an active hospital radiology practice, to function as your President. Mrs. Bader will retire as Executive Director of the Medical Society of Delaware in June of 1989 after many years of outstanding service to this Society. The Search Committee, in a detailed and thorough screening process, selected Mr. Mark Meister, currently Executive Vice President of the Health Plan of Central Illinois, as new Executive Director. Mr. Meister, who will join us in May, is a superior and capable young man with an impressive background in health and medical administration. Mrs. Bader will continue to head the Medical Society of Delaware Insurance Subsidiary.

I wish to thank you, the physicians of the Medical Society of Delaware, for the honor and the privilege of service you have bestowed on me as President during the 199th year of the Medical Society of Delaware. I have endeavored at all times to act in the best interest of our Society and our patient constituency. If called upon, I stand ready to assist and support our new President and the Society in the future.

Martin J. Cosgrove, M.D.
President

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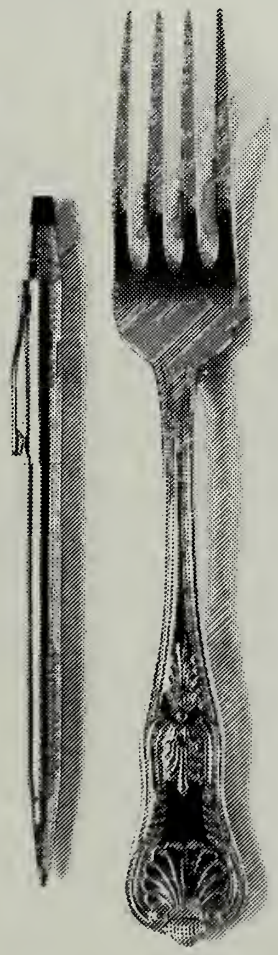

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DELAWARE
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ADVANCES IN THE DRUG MANAGEMENT OF RHEUMATOID ARTHRITIS

John H. Klippel, M.D.
Jeffery Shiroky, M.D.

Introduction

Rheumatoid arthritis (RA) is the most common of the chronic, inflammatory, destructive arthropathies. The consequences of progressive disease are devastating and include pain, functional disability with alarming economic losses and, as has been recently recognized, accelerated patient mortality. These have served to stimulate interest in the development of newer approaches to the therapy of the disease. Over the past decade, a number of major advances likely to have a significant impact in future drug management have been introduced. Several of the more important of these drug therapies are considered in this review.

Methotrexate

The beneficial clinical effects of the folic acid antagonist aminopterin in RA were originally described by Gubner and colleagues in 1951.[1] The report generated little interest at the time, largely as a result of the dramatic effects produced by corticosteroid hormones discovered only a few years earlier. With the recognition that corticosteroids were not a cure and were often associated with serious adverse toxicities, attention refocused on alternate approaches to drug management of the disease. Over the past two decades, low dose, intermittent methotrexate has been gradually rediscovered and has clearly become a major advance in the drug therapy of RA. To date, methotrexate remains an investigational agent not approved by the Federal Drug Administration for use in RA.

A profile of the pharmacology, contraindications, and principle toxicities of low dose methotrexate is shown in Table 1. The relevant mechanism of drug action important in RA has not been identified. Clinical observations of prompt improvement in disease after institution of the drug, and conversely, a rapid disease flare upon discontinuation, imply a primary antiinflammatory action. The drug has been extensively studied in short term, randomized, controlled trials in which efficacy far superior to placebo has been easily demonstrated.[2] In comparison to approved conventional disease modifying drugs,

Dr. Klippel is Clinical Director, Arthritis and Rheumatism Branch, National Institute of Arthritis, Musculoskeletal and Skin Diseases, Bethesda, Maryland.
Dr. Shiroky is with the Division of Rheumatology, The Montreal General Hospital, Montreal, Quebec.

Table 1
Low-dose, intermittent methotrexate in rheumatoid arthritis

Route/Dose:	Oral, intramuscular; 5-25 mg weekly. Most common drug schedules include: a) Oral divided weekly, typically 3 doses at 12 hour intervals, b) Oral single dose weekly, and c) Intravenous single dose weekly.
Kinetics/Metabolism:	Well absorbed, ► 50% bound to plasma proteins, excreted by kidney via glomerular filtration and distal tubular secretion. Actively transported into cells, converted to polyglutamate which binds to and inactivates the intracellular enzyme dihydrofolate reductase.
Drug Interactions:	Displaced from serum proteins by salicylates and other non-steroidal antiinflammatory drugs, phenytoin, sulfonamides, tetracycline, and other drugs.
Contraindications:	Pregnancy, acute/chronic liver or pulmonary disease, alcoholism, severe anemia/leukopenia, impaired renal function, infection.
Principal Toxicities:	Minor: GI intolerance, stomatitis, fever, hepatitis, rash. Major: Cirrhosis, pneumonitis, pancytopenia, fetal abnormalities.

methotrexate appears to be comparable to gold sodium thiomalate and azathioprine. The long term effects of the drug are largely unknown. The available data concerning drug effects on radiographic progression, the traditional standard used to judge efficacy of disease modifying drugs in RA, suggest that methotrexate does not influence cartilage loss or erosive bone destruction.[3]

Toxicities from low dose, intermittent methotrexate necessitate discontinuation of the drug in approximately 20% of patients. Minor toxicities including gastrointestinal side effects such as nausea, anorexia, vomiting and diarrhea, stomatitis, and hepatitis are frequent and typically reversible with drug withdrawal. The principle major serious toxicities of methotrexate involve hepatic and pulmonary complications. In psoriasis, chronic, low dose methotrexate has been associated with cirrhosis. Cumulative drug dose is considered to be an important factor with an estimated 3-5% risk of cirrhosis following 1.5 grams of the drug. Serum elevations of liver enzymes correlate poorly with serious liver pathology and are thus unreliable clinical monitors of serious methotrexate liver toxicity. Liver biopsy studies in patients with RA treated with methotrexate have documented various grades of hepatic fibrosis in 5-10% of patients. To date, however, there have been no reports of actual cirrhosis in these patients.

Acute, life threatening pulmonary toxicities have been described: an alveolar toxic process, and a hypersensitivity-like reaction with interstitial pneumonitis, granuloma formation, and bronchiolitis. Bronchial lavage or lung biopsy is often necessary to exclude an infectious etiology. Methotrexate has been associated with fetal abnormalities and is clearly contraindicated during, or in anticipation of, pregnancy. There is no evidence that low dose, intermittent methotrexate is associated with an increased risk of malignancy.

Sulfasalazine

Sulfasalazine was synthesized by Svartz specifically for the treatment of RA.[4] Speculating that an unidentified infectious agent was likely responsible for the disease, it was reasoned that a drug which combined the antiinflammatory properties of a salicylate along with the antibacterial properties of a sulfonamide might prove to be efficacious. To that end, sulfapyridine was linked to 5-aminosalicylic acid via an azo bond to yield the compound sulfasalazine.

The initial clinical studies of sulfasalazine emphasized the possible beneficial effects of the drug in both RA as well as in ulcerative colitis. Although sulfasalazine rather promptly became an accepted standard therapy for inflammatory bowel diseases, its importance in RA was largely ignored for several decades until the rediscovery of the drug by McConkey and colleagues.[5] Convincing evidence of drug efficacy in RA has emerged from several controlled trials in which sulfasalazine has been compared to placebo, D-penicillamine, and gold sodium thiomalate.[6] In general, sulfasalazine has been found to be far superior to placebo and has similar efficacy to other disease modifying agents. The Federal Drug Administration has not approved sulfasalazine for use in RA and, as such, the drug would be considered an investigational agent in this disease.

Table 2
Sulfasalazine in rheumatoid arthritis

Route/Dose:	Oral, 1-3 g daily. Initial dose of 500 mg daily increased by 500 mg increments each week given on B.I.D. schedule.
Kinetics/Metabolism:	– 30% absorbed in small bowel with enterohepatic circulation. Cleaved in colon to sulfapyridine (SP) and 5-aminosalicylic acid (5-ASA). SP absorbed, acetylated in liver and excreted in kidney; 5-ASA mostly excreted in feces.
Drug Interactions:	Decreased gut metabollism/absorption with concurrent antibiotic use, interferes with folic acid absorption, decreases bioavailability of digoxin.
Contraindications:	Sulfonamide allergy.
Principal Toxicities:	Minor: GI intolerance, mucocutaneous reactions, leukopenia, hepatitis, central nervous system dysfunction. Major: Agranulocytosis, pneumonitis, oligospermia/ infertility

A summary of the pharmacokinetics of sulfasalazine is displayed in Table 2.[7] Drug absorption occurs in both the small bowel with enterohepatic circulation as well as in the colon following enzymatic degradation of the drug. Serum levels of 5-aminosalicylic acid are negligible, with most of the drug excreted unchanged in the feces. The sulfapyridine is well absorbed, evenly distributed throughout the body, and excreted in the urine. Sulfapyridine appears to be the principle active metabolite in suppression of arthritis activity, although the relevant mechanism of action has not been established. Among the many properties of sulfapyridine described, inhibition of prostaglandin synthesis through effects on the lipoxygenase pathway and prostaglandin F2 breakdown, inhibition of migration and proteolytic enzyme activity of polymorphonuclear leukocytes, and immunomodulating effects may contribute to the clinical antirheumatic effects observed.

Adverse reactions from sulfasalazine appear to be common, and account for a withdrawal rate of 20-30%. Gastrointestinal complaints including nausea, vomiting, anorexia, and abdominal pain are most frequent. These are thought to be secondary to drug effects on the central nervous system. Leukopenia may develop, and frequent monitoring of the white blood cell count with appropriate dose adjustments as required is essential. Maculopapular rashes are not uncommon, and patients with known allergic reactions to sulfonamides should not be treated with the drug. Reversible changes in sperm count, motility, and morphology have been described. Rare idiosyncratic reactions including blood dyscrasias, toxic hepatitis, and interstitial pneumonitis are the principle serious toxicities.

Combination Chemotherapy

The concept of combination chemotherapy has been a traditional cornerstone in the drug management of progressive, severe RA. Antiinflammatory drugs to suppress inflammation at the level of the synovium are typically combined with single, so-called disease modifying or second line drugs like gold, hydroxychloroquine, D-Penicillamine, or azathioprine. In the 1980s, combination chemotherapy of RA has come to assume a new meaning in which combinations of second line agents themselves are employed. Synergistic drug combinations should allow for dose reduction of individual constituent drugs and thus minimize the risks of dose-dependent drug toxicities, often a limiting factor in therapy.

Theoretically, drugs which act on independent pathologic processes involved in RA would prove to be most effective. However, the task of selecting rational drug combinations has been hindered by the absence of detailed knowledge as to the exact mechanism of action of most of the current disease modifying drugs. The approach employed to date, therefore, has been a clinical trial and error type method involving various combinations of many of the conventional agents. Examples include combinations of hydroxychloro quine with gold and D-penicillamine, cyclophosphamide and methotrexate, and cyclophosphamide and azathioprine. Evidence of the potential efficacy of combination chemotherapy in RA is particularly apparent with this latter combination with disease remission has been reported in over one half of the patients, and documentation of recortication of bone erosions in nearly 90% of patients.[8] However, toxicities from this combination developed in 80% of patients and included four patients who developed serious malignancies. The investigators themselves concluded that the toxicities were unac-

ceptable and that cyclophosphamide, perhaps the most effective known drug in the treatment of RA, should not be included in other studies of combination chemotherapy.

In summary, combination chemotherapy is an attractive, unproven approach to the drug management of RA. Future controlled trials in which drug combinations are directly compared to the individual component drugs given in identical doses are essential for advancements in this field.

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Carcinogenesis, Mutagenesis, Impairment of Fertility: Chronic oral toxicity studies of 24 months' duration were conducted in mice and rats at doses up to 1 gm/kg (12 times the human dose). There was no evidence of drug-related tumorigenicity. A reproduction study in rats at doses up to 38 times the human dose did not reveal any indication of fertility impairment. Mutagenicity studies were not conducted.

Pregnancy: Teratogenic effects. Pregnancy Category B. Teratogenicity studies have been performed in mice, rats, and rabbits at doses up to 50 times the human dose and have revealed no evidence of harm to the fetus due to sucralfate. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when sucralfate is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Adverse reactions to sucralfate in clinical trials were minor and only rarely led to discontinuation of the drug. In studies involving over 2,500 patients treated with sucralfate, adverse effects were reported in 121 (4.7%).

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OVERDOSAGE

There is no experience in humans with overdosage. Acute oral toxicity studies in animals, however, using doses up to 12 gm/kg body weight, could not find a lethal dose. Risks associated with overdosage should, therefore, be minimal.

DOSAGE AND ADMINISTRATION

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Antacids may be prescribed as needed for relief of pain but should not be taken within one-half hour before or after sucralfate.

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GROWING PAINS

Robert A. Doughty, M.D., Ph.D.

Introduction

Growing pains are a source of confusion, misdiagnosis, and inappropriate treatment among parents, allied health professionals, and physicians. As the definition is quite variable, it is not surprising that the term "growing pains" is often inaccurately applied. Take, for example, the definition given in Webster's Second New Collegiate Dictionary in 1960: "growing pains: neuralgic pains or cramp in the limbs occurring during growth (rarely in singular)".[1] This contrasts sharply with the definition of the Seventh New Collegiate Dictionary in 1963: "...pains in the legs of growing children having no demonstrable relation to growth,"[2] and further varies from that of 1981: "...growing pains [are] pains in the legs of children caused by fatigue, postural defects, emotional disturbances, or other factors having no demonstrable relation to growth."[3] Interestingly, Dorland's Medical Dictionary excludes the term entirely.

It is still not clear whether growing pains is a single diagnosis or a collection of diagnoses with similar symptoms. Most pediatricians and family practitioners see children who are diagnosed as having growing pains. This article will attempt to shed some light on this common condition and suggest an approach to its diagnosis and management.

The term is attributed to Duchamp, who first used it in 1823.[4] It was not strictly defined, however, until 1951, when Naish and Apley carefully studied the incidence of musculoskeletal complaints in a population of 721 British school children.[5] Using a definition of pain of at least three months duration, not specifically localized to joints, and causing some interruption of normal activity, they found such a condition to affect 5% of the children studied. It appeared to be benign over a three year follow-up. They did identify an inheritable pattern and noted that there was a family history of "rheumatic pain" in half the children, versus 10% of controls.

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Case Example

Growing pains are a common problem for those who treat children. The following case serves to demonstrate the common pattern of presentation.

Jimmy, an active five year old child, presented to pediatric rheumatology clinic for evaluation because of a two year history of lower extremity pains. The pains usually occurred at night and would waken him, crying, from sleep, often several times per week. They were poorly localized and variably involved the calves, the thigh, or the knees. The child seemed to feel better when either parent massaged the affected area. Occasionally salicylates helped, often within minutes. The mother reported that she could occasionally note "a little swelling," but the father was less certain of this, and neither swelling nor limp was evident the next morning. Both parents were very confused as to the cause of the problem and con-

cerned that there was a serious underlying diagnosis which physicians kept missing. A maternal grandmother had severe rheumatoid arthritis.

The patient had been seen by his family physician, an orthopedist, a physical therapist, a podiatrist, and had had multiple diagnostic studies performed, including x-rays of both lower extremities, a complete blood count, sedimentation rate, muscle enzymes, antinuclear antibody, rheumatoid factor, and a bone scan. Flat feet were initially identified as the cause of the pain, but recent speculation had raised the possibility of juvenile rheumatoid arthritis.

The child's examination was entirely normal despite having had a bout of symptoms the previous evening. A diagnosis of growing pains was made and the parents were reassured that the condition was benign. A program to modify their child's complaints was outlined. Two months later the symptoms had largely disappeared, although the child still occasionally experiences musculoskeletal symptoms following strenuous physical endeavors.

Growing pains is basically a diagnosis by exclusion. A reasonable definition is:

> Intermittent pains or aches localized (usually) to the legs occurring over several months to years in children between the ages of three and 12 with no definable medical pathology.

Clinical Presentation

The common sites of the pain are the soft tissues of the thigh, calf, or popliteal fossa. Less common sites are the arms, shoulders, groin, back, and instep. It is not usually specifically localized to the joints. Bilaterality is often present and is helpful in differentiating from focal, potentially pathological processes. Some children experience a feeling of restlessness in the legs. The overall prevalence of the condition may be as high as 20%, with girls having a slightly greater overall incidence than boys and a slightly older age of onset (peak age is nine to 12). There is a tendency for parents of patients to have had growing pains as a child. Extensive physical activity may be associated with an increased incidence of symptoms. The pains usually occur late in the day, in the evening, or awaken the child at night. The child is invariably physically normal in the morning. The frequency varies from once a day to several times per month. Attacks may last for years, but eventually subside.[6-7]

Pertinent negatives on history include absence of limp; normal range of motion of joints; no swelling, warmth, or tenderness of joints; absence of systemic signs of illness such as fever, weight loss, temperature change of extremity, muscle wasting, abnormal cardiac murmur, or abnormal neuromuscular examination; no interference with activity; and no morning stiffness. A variety of conditions have been noted to be closely associated with, if not actually causally related to growing pains, including growth spurts, myalgia from muscle strain, rheumatic conditions, recovery from viral disease, fibromyositis, onset of puberty, inclement weather, inadequate or altered sleep patterns, genetic factors, flat footedness, food allergy, emotional stress, and postural or orthopedic defects. No clear pathogenesis has ever been established for any of these associations.[8]

Differential Diagnosis

Although many diagnoses need to be considered early as possible causes of non-specific musculoskeletal symptoms in a child, with the passage of time the likelihood of a specific serious diagnosis being responsible substantially decreases. Some of the diagnoses which may masquerade early as growing pains and should be considered in the differential diagnosis are:

Juvenile rheumatoid arthritis. Affected children usually present with objective arthritis and often have fever or signs of systemic illness. The antinuclear antibody may be positive.

Acute rheumatic fever. Patients usually have an abnormal cardiac murmur, evidence of antecedent streptococcal infection and objective arthritis.

Dermatomyositis/Polymyositis. Children present (usually) with proximal muscle weakness, characteristic skin rash, serum muscle enzyme abnormalities, and evidence of systemic illness.

Leukemia. Patients may have vague bone pain, but usually have fever, weight loss, anemia, and roentgenographic abnormality (periostitis).

Legg-Calve-Perthes Disease. The hip range of motion is abnormal.

Osgood-Schlatter Disease. Tenderness is focal over the tibial tubercle.

Slipped capital femoral epiphysis. This occurs in obese adolescents with an abnormal hip examination.

Osteoid osteoma. Affected children present with focal, nocturnal pain which is localized to the tibia or fibula, is sensitive to salicylates, and has an abnormal bone scan.

Osteomyelitis. The pain is usually unifocal with fever, leukocytosis, roentgenographic or bone scan abnormality.

Sickle Cell Disease. Family history may be suggestive, but this should be considered in all black children.

Thrombophlebitis/phlebothrombosis. Physical findings usually reveal a difference in extremity circumference, palpable cord or focal tenderness, and pain in the morning.

Sacral abscess. This may present with vague referred pain but patients usually have fever and abdominal or bladder symptoms.

Lumbosacral spinal infection or tumor. These patients may have neurological signs, elevated sedimentation rate, leukocytosis, and roentgenographic or bone scan abnormality.

Infectious or Degenerative Neuromuscular Disease. These include Duchenne's, myasthenia gravis, poliomyelitis, or discitis. Patients usually have a persistent limp or neurological abnormalities.

Reflex Sympathetic Dystrophy. This presents with exaggerated chronic pain which persists throughout the day.

Benign hypermobile joint syndrome of childhood. There is hyperextensibility due to ligamentous laxity with associated musculoskeletal complaints and may account for 50% of children with growing pains.

History and Physical Examination

Having covered the differential diagnoses of a child with possible growing pains, what is a logical approach to the child's evaluation? First, a careful history should be taken, with special attention to the orthopedic and neuromuscular systems. Attention should also be paid to behavioral aspects of the symptoms, but this should not be overemphasized at this point until serious diagnoses have been eliminated. Next, a careful physical examination should be performed, preferably shortly after, or even better during, an episode of symptoms.

Evidence for objective arthritis should be sought, such as warmth, swelling, limitation of, or pain on joint motion; muscle wasting or asymmetry. Gait should be carefully observed. Muscles should be palpated for tenderness, and strength tested for symmetry and evidence of weakness.

Laboratory Studies

Assuming the history points toward a possible diagnosis of growing pains and the physical examination is normal, laboratory studies can usually be limited in extent. It is usually advisable to obtain as a minimum a complete blood count and erythrocyte sedimentation rate. If the pain is focal or unilateral, a normal roentgenogram is reassuring. Hemoglobin electrophoresis should be done if a hemoglobinopathy is suspected. Rheumatologic serologies such as antinuclear antibody or rheumatoid factor are usually not warranted. Optional diagnostic studies which may be useful depending upon the patient's presentation include: muscle enzymes (CPK, SGOT, and aldolase) as a screen for muscle inflammation; antinuclear antibody (ANA) as a screen for rheumatologic disease (only 25% sensitivity); gallium or technetium scan as a screen for suspected infection, osteoid osteoma, or tumor; and computerized tomography or magnetic resonance imaging for suspected pelvic mass or cord lesions.

Therapy

Once a diagnosis of growing pains is established by exclusion, therapy should consist of reassurance, distraction, and de-emphasis. Optional therapies include heat, massage, salicylates or non-steroidal anti-inflammatory drugs. Longitudinal follow-up is required, with periodic repeat physical examination and/or laboratory studies, to reassure the physician and parents that the diagnosis of growing pains is correct.

The key to successful therapy is addressing all of the family's concerns. By obtaining a careful psychosocial history, the physician can determine the extent to which the symptoms are being overemphasized and reinforced. Some of the red flags which may emerge follow.

- Does this represent the vulnerable child syndrome? Musculoskeletal complaints may be the focus for a parent's unresolved anxieties about the child's general health due to a previous serious illness or unexplained or unresolved prior medical condition.

- Is the child having difficulty in school, and do the symptoms function to help the child avoid dealing with other life issues?
- Are the child's complaints similar to unresolved physical complaints from which a parent suffers?
- Has there been a recent death of a parent or relative, separation from a significant person (eg, school friend, grandparent, pet) or a recent marital discord as a source of family stress?
- What is the child's concern about the diagnosis? Many children experienced excessive focusing on musculoskeletal symptoms due to anxiety generated by the osteosarcoma and surrounding publicity involving Senator Kennedy's son.
- Do the parents feel that "this child only complains of pain when it is really bad" because of the child's previous indifference to somatic com plaints, and have they been hovering and overly focusing attention on otherwise trivial complaints?

Conclusion

The most important aspect of the management of growing pains is to continue to follow the family and keep an open mind about the possibility of something changing in the clinical picture which may warrant a fresh look or further investigation. In most cases, the complaints will diminish with time. However, if physical abnormalities do develop, the clinician must pursue appropriate further diagnostic testing. In the absence of such a development, however, the more time that passes, the more likely it is that the diagnosis of growing pains is indeed correct and that the ultimate prognosis is for complete resolution of the symptoms.

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THE WOLF INSIDE

John Stone, M.D.

Four weeks before she died of a complication of lupus erythematosus, Flannery O'Connor wrote: "The wolf, I'm afraid, is inside tearing up the place. I've been in the hospital 50 days already this year." By the time of her next recorded letter, three days later, she had received the rite of Extreme Unction. I never met Flannery O'Connor, but I never see a patient with lupus now without thinking of those words and of the woman herself.

The word *lupus* was appropriated whole to the medical vocabulary directly from the Latin; it means "wolf." This autoimmune-system disease affects virtually every organ in the body. About 60% of patients have a red ("erythematous") rash on the face, over the bridge of the nose and on the cheeks below the eyes, in a more or less "butterfly" pattern, a shape similar to the facial markings of a wolf.

I saw a young woman with lupus today. She doesn't have the rash. She does have extensive kidney disease and, according to an x-ray, a massively enlarged heart. Hers is a dramatic case. In just two months, she has gained 50 pounds, all of it water. I shake her hand. As she tells her story, it's obvious that she is reasonably comfortable. She's breathing easily, her blood pressure and pulse are good. Since I was first asked to see her, I have also learned that, despite the x-ray, her heart is not enlarged. Rather, the pericardial sac around it, designed to hold a scant ounce of fluid, has managed to stretch hugely, accumulating three quarts of fluid--thus the enlarged heart shadow on her x-ray. She is waterlogged, her tissues swimming in excess fluid. The echocardiograph is like a sonar unit, its echo like the sonogram of a fetus: but instead of a fetus floating within its sac of liquid, there was her heart, normal in size, bobbing and squeezing like a fist.

Her kidney disease is such that she is losing huge amounts of protein in the urine. Normal kidneys filter the total blood volume many times each day, losing into the urine only tiny amounts of protein. Her kidneys are leaking protein like a sieve. Without that protein, there is nothing to hold the plasma within the blood. The kidneys are also leaking water into all her tissues, including the pericardial sac. After talking with her at length about her illness, I examine her. A soft, scratchy noise, synchronous with the heartbeat, confirms her inflamed pericardium. Her legs are grossly swollen. I press my fingers gently into the skin over her shins--the tips of my fingers sink in as though they were poking the soft belly of the puffy little doughboy in the television ad. Several minutes later, as I leave, the deep pits are still there.

Prednisone, a form of cortisone, has been started. The hope is that, in massive doses, it will help seal the protein leaks of her kidneys, and that diuretics will mobilize the 50 pounds of excess fluid.

Dr Stone is a cardiologist at the Emory University School of Medicine, and a published poet.

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The immediate question is whether to use a needle to draw off the fluid from around her heart. The danger is that the fluid will restrict and restrain the heart's action, like the cellophane wrapper on a box of valentine candy, and jeopardize its all-important pumping. I decide we should not attempt to remove the fluid now, reasoning that it will only reaccumulate: the dike has multiple holes in it--the water would seep back in. The cardiology fellows working with me disagree. They are in favor of the needle. I argue that we should wait for the drugs to work. I worry about her as I go to sleep that night; it is often easier to *do* something, rather than wait, but it's not always best for the patient. We keep a sterile tray, with a long pericardial needle in it, at her bedside, just in case.

Flannery O'Connor had lupus for some 14 years before she imagined the wolf tearing up the place. The disease had begun, in late 1950, with, as she spells it, "awthritus." Arthritis, or joint pain, is present in 90% of patients with lupus. Just as common is an overwhelming fatigue, often accompanied by fever, loss of appetite and loss of weight. The exact cause of lupus is uncertain, but it is known that in the course of the disease the body makes antibodies directed against and damaging to its own organs. The process amounts to a kind of immunological betrayal of its owner by the body, an absolute autoimmune revolution. Lupus is primarily a disease of women (90% of cases, with a peak incidence in the childbearing years). Flannery O'Connor's father died of lupus, however, and today, human lymphocyte antigen (HLA) typing, a kind of tissue "matching" that is done for organ transplants, confirms that there may be a genetic predisposition. New drugs to suppress the immune system help slow progression of the disease and also reduce the requirements for steroids, such as cortisone, with their side effects. But lupus is capricious, with both relapses and remissions: statistically, the majority of patients can look forward to a time when they will be relatively free of problems.

But Flannery O'Connor had a severe case: clearly, the wolf *was* inside. Sally Fitzgerald, editor of O'Connor's letters, speaks movingly of the time, late in 1950, when she learned from Flannery's mother "that Flannery was dying of lupus": "The doctor minced no words. We were stunned. We communicated regularly with Mrs. O'Connor while she went through this terrible time and the days of uncertainty that followed, during Dr. Arthur J. Merrill's tremendous effort to save Flannery's life."

Dr. Merrill, Flannery's physician, is a former mentor of mine. About 20 years ago he told me that Flannery's lupus was diagnosed just as more helpful therapy became available (eg, in 1949, P.S. Hench and co-workers reported the efficacy of ACTH and cortisone in arthritis). ACTH, a hormone that causes the body to secrete cortisone, was prescribed for Flannery in the early 1950s. The effect of ACTH (and cortisone, which she took later) is to blunt the body's response to the turncoat antibodies. The drugs worked--at a price. ACTH and cortisone can have significant side effects: thinning of bone (osteoporosis); loss of muscle strength; a "moonlike" shape to the face; exacerbation of duodenal ulcers; altered metabolism; increased susceptibility to infections; mood changes, ranging from a feeling of well-being to depression and even psychosis.

Flannery was well aware of the side effects as she wrote: "My dose of prednisone has been cut in half on Dr. Merrill's orders, because the nitrogen content of the blood has increased by a third. So far as I can see, the medicine and the disease run neck & neck to kill you." But she felt better on the medications. In 1960, after ten years of steroids, she wrote: "...as Dr. Merrill says, it is better to be alive with joint trouble than dead without it. Amen."

Over the next week, as I see my own young lupus patient, I can tell, thank God and prednisone, she is improving. She has lost more than 30 pounds, all of it water. The pericardial fluid has diminished--her echo looks better. She's going to make it. And she gives me a tired, heroic smile.

Heroic is, I think, the word for Flannery O'Connor, too. When the disease struck her, she was 25, a graduate of the Iowa Writers' Workshop, a fledgling writer just beginning to make a name for herself. Despite the wolf, the next 14 years were productive: she won three O. Henry prizes; the National Book Award came posthumously, in 1971. Many of her best short stories were written then: "A Good Man Is Hard to Find," in 1953; "Good Country People," 1955; "Everything That Rises Must Converge," 1961; "Revelation," in 1964; just months before she died.

Flannery O'Connor knew at least two kinds of isolation--that required by her craft, and that im-

posed by her illness. Listen to her in 1956: "I have never been anywhere but sick. In a sense sickness is a place, more instructive than a long trip to Europe, and it's always a place where there's no company, where nobody can follow." Of course, in a metaphorical sense, Flannery C'Connor never stopped traveling. And the joy of discovery kept her at the typewriter. From one of the earliest of her collective letters (July 21, 1948), there is evidence that the process of writing was, for her, journey enough: "...I have to write to discover what I am doing. Like the old lady, I don't know so well what I think until I see what I say..."

Flannery O'Connor *endured*, to use Faulkner's term, despite the lupus. That she weathered the devastating side effects of ACTH and cortisone, continuing to write, slowly, painfully, to find out exactly what she *did* think, makes her a heroine to me. But, then, many of my patients seem heroic to me, especially the ones with chronic illnesses.

Through its Latin root, the word *doctor* means teacher, but very often it is the patient who does the teaching, especially when the lesson is one in courage. It's one thing to have an acute, limited, illness, to pass the bloody agonizing kidney stone and be done with it; it's quite another to go to sleep with pain, to dream that it's gone, then wake back up to the same pain waiting like a wild beast at the foot of your bed. And to persevere despite the pain, feeling it flow like electricity out of your forearms along your sore wrists and out to your stiff fingers to discover precisely how the 26 letters of the alphabet plan to marry *this* time.

Lupus betrayed Flannery O'Connor like a sophisticated Trojan horse, one with a wolf inside. Once within the body's gates, the enemy was everywhere. Still, she prevailed, even if it was only until her 39th year. And her life and words are a study in keeping on keeping on. It is in that spirit that I move to the next patient.

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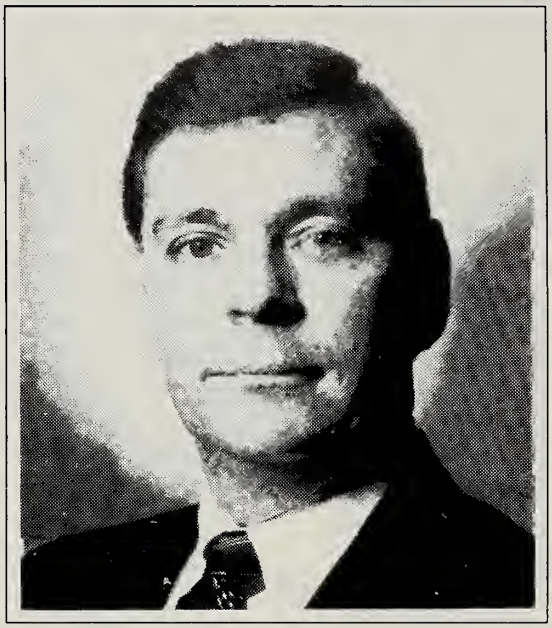

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LYME DISEASE: A HISTORICAL PERSPECTIVE

James H. Newman, M.D.

Historical Background

Erythema chronicum migrans (ECM) is a red, expanding, mildly uncomfortable skin lesion that can grow to be very large. The periphery remains red while frequently, the central portion begins to clear. This skin lesion was first described in Sweden in 1910, and again in Germany in 1913.[1] Initially thought to be the consequence of the bite of a sheep tick, it was also felt to be infectious, since inoculation of scrapings from the border of the lesion into the subcutaneous tissue of another person could reproduce the lesion.

Eleven years after its initial description, ECM was first associated with neurologic disease: specifically, meningitis and peripheral nerve symptoms. This observation was confirmed in 1941, when the typical triad of meningitis, cranial nerve palsies, and peripheral nerve symptoms, including radiculitis, plexitis, and peripheral neuropathy, was described. By the early 1970s, the syndrome of ECM and neurologic disease was well described in the European literature and referred to as tick-borne meningopolyneuritis. Arthritis had never been mentioned as a feature of this syndrome.

Erythema chronicum migrans was first described in the United States in 1970 in Wisconsin, and in 1972 in Connecticut.

An intriguing side note shows that in the late 1940s, a German investigator thought he observed spirochetes in special stains of the skin lesion by using a silver impregnation technique. His observation was not confirmed with phase contrast and dark field microscopy, and passed into oblivion.

Dr. Newman is a rheumatologist with a private practice in Wilmington.

Initial Discovery of Lyme Disease

In November 1985, two separate but related incidents occurred which clued Allen Steere, M.D. of Yale University, to the possibility that an unusual phenomenon was occurring in Eastern Connecticut in the communities of Old Lyme, Lyme, and East Haddam.[2] The Connecticut State Department of Public Health had been notified by a mother that within a short period of time, a number of children living close to one another had been diagnosed with rheumatoid arthritis. The information was passed on to Dr. Steere. Within three days of this phone call, Dr. Steere saw a family from the same area in which both adults and two children were affected by recurring attacks of inflammatory arthritis. Realizing that a cluster of arthritis occurring in adults and children was unusual, he organized an epidemiologic study in these communities in the winter and early spring of 1975. He was able to identify 51 patients who had been having recurrent attacks of monoarticular or pauciarticular arthritis dating back to 1972. Twenty-five percent of these initial patients recalled a peculiar skin lesion, which by description matched ECM, preceding the onset of their arthritis. One of the patients recalled a tick bite preceding the onset of the skin lesion.

Using this information, Dr. Steere initiated a surveillance study in these communities in the spring of 1976, enlisting the help of local primary care physicians.

Surveillance Studies

During the first summer of the surveillance study, Dr. Steere saw 32 patients with either ECM or arthritis.[3] His clinical observations regarding this small group of patients became the foundation of our understanding of Lyme disease. Three of the patients remembered that the skin lesion was preceded by a tick bite. The patients had a flu-like illness accompanying the skin lesion, characterized by malaise, fatigue, variable fever, headache, sore throat, and nonspecific gastrointestinal symptoms. Five to ten percent of these patients were observed to evolve significant neurologic disease, characterized by either lymphocytic meningitis, cranial nerve palsies, and/or peripheral nerve symptoms. The most common neurological abnormality was unilateral or bilateral seventh nerve palsy. Heart involvement, characterized by varying degrees of heart block, also developed in 5-10%. Two thirds of the patients went on to develop arthritis.

There were no laboratory peculiarities regarding these patients with the pertinent exception that the majority manifested cryoimmunoglobulins and elevated levels of serum IgM and that the ones who had the most significant cryoglobulins with ECM were more likely subsequently to have arthritis.

Many attempts were made to culture or obtain serologic evidence for infection, but none was found.

In the spring, summer, and fall of 1977, Dr. Steere studied an additional 43 patients with Lyme disease.[4] Of those, 21% could recall a tick bite preceding ECM. One patient brought in a tick, subsequently identified as *Ixodes scapularis*, a cousin of the sheep tick thought to transmit ECM in Europe. That second summer was devoted to furthering the understanding of the epidemiology of the syndrome, and it was concluded that Lyme disease was an illness very likely transmitted by *I. scapularis*.

In 1978, 48 more patients were added to the Lyme disease clinic. The direction of clinical research turned toward extending the immunologic aspects of Lyme disease.[5] The predictive value of cryoglobulins, elevated serum IgM, and the presence of circulating immune complexes confirmed the likelihood of subsequent neurologic, cardiac, and especially arthritic manifestations. In addition, ten patients were studied who had gone on to a more chronic destructive synovitis in the knee. These patients developed pannus which was similar histologically and biologically to what was seen in rheumatoid arthritis. There seemed to be an immunogenetic predisposition to developing this chronic type of arthritis in Lyme disease.[6]

The 1978 season found *I. scapularis* in Connecticut to be morphologically distinct, and was reclassified as *Ixodes dammini*. The distribution of Lyme disease was also wider than had previously been appreciated, with additional states in the Northeast Corridor as well as Wisconsin, California, and Oregon added to the regions in which Lyme disease was reported. In each area, Ixodid ticks were known to exist. Finally, neurologic manifestations were carefully detailed in preparation for reporting and were found to be quite similar to the clinical spectrum of tick-borne meningopolyneuritis associated with ECM in Europe.

In 1979, tetracycline, penicillin, and erythromycin were used widely at the Yale Lyme Disease Clinic to treat ECM. The justification for this was the European observation that these antibiotics shortened the course of the skin rash. The experience of that summer and preceding years, which was a non-randomized uncontrolled observation, was subsequently published in July of 1980,[7] strongly suggesting that antibiotics shorten the duration of the skin lesion and associated acute illness, and seem to reduce the likelihood of subsequent arthritis. This observation was received with some skepticism.

Mystery of Lyme Disease Solved

In 1982, Willy Burgdorfer, reporting in the journal *Science*, identified spirochetes from *I. dammini* ticks provided for him from Shelter Island, New York.[8] Patients with Lyme disease manifested antibodies by direct immunofloresence against these spirochetes. Initially, the bacteria were referred to as the Lyme disease spirochete, but later were named *Borrelia burgdorferi*. They seemed to have morphologic and microbiologic characteristics that were halfway between *Treponema pallidum* (known to cause syphilis in man) and the *Borrelia* species (known to cause relapsing fever in man). They could be cultured with some difficulty using a modified Kelly's medium.

Dr. Steere and his Yale colleagues subsequently identified these spirochetes in plasma,

cerebrospinal fluid, and a skin lesion from three patients.[9] In addition, Dr. Steere demonstrated antibodies to *B. burgdorferi* in the stored sera of his patients with Lyme disease.

Rounding Out the Picture

By mid-1983, Dr. Steere had reviewed the clinical manifestations of Lyme disease over the initial seven years of its existence.[1] He showed by studies done in the early 1980s that the skin lesion did in fact respond to antibiotic intervention, and that the use of tetracycline in particular seemed to prevent the subsequent development of arthritis. He also reported successful treatment regimens using high dose intravenous penicillin for severe neurologic disease.[10]

In 1985, the spirochete had been observed to persist in the synovium of patients with Lyme arthritis and had been cultured from synovium as well. Finally, Dr. Steere reported the successful treatment of Lyme arthritis by using several different antibiotic regimens.[11]

Significance of Lyme Disease

It is a common assumption by rheumatologists that some forms of inflammatory arthritis, such as rheumatoid arthritis, are the consequence of a trigger event initiating a persisting immunologic reaction in an immunogenetically susceptible host. This event leads to an inflammatory response within joints that causes the destructive pannus we see in rheumatoid arthritis. One of the great problems in studying rheumatoid arthritis is that we only can observe the illness from the beginning of the patient's symptoms. The trigger event, which may be one of several different types of infections, may occur weeks, months, or even years before the onset of symptoms. This is why it is so difficult to know what may cause the rheumatoid process to begin.

Lyme arthritis appears to look similar clinically, histologically, and biologically to rheumatoid arthritis. In this instance, however, the trigger event is well known and involves an infection with a bacterium which appears to localize in synovium and persists in small numbers in a viable manner. This bacterium can initiate an immune response and lead to an inflammatory picture very similar to rheumatoid and other types of inflammatory arthritis. Furthermore, clinical recognition of Lyme arthritis and its treatment with antibiotics can apparently lead to cure. Therefore, it is an important model for the understanding and investigation of rheumatoid and other types of inflammatory arthritis.

Delaware physicians should maintain a high index of suspicion when they see patients with heart block, meningitis, cranial nerve palsy, peripheral nerve symptoms, or recurring arthritis. This constellation could represent Lyme disease, a treatable illness. Diagnosis can often be made by careful history, examination, and serologic study.

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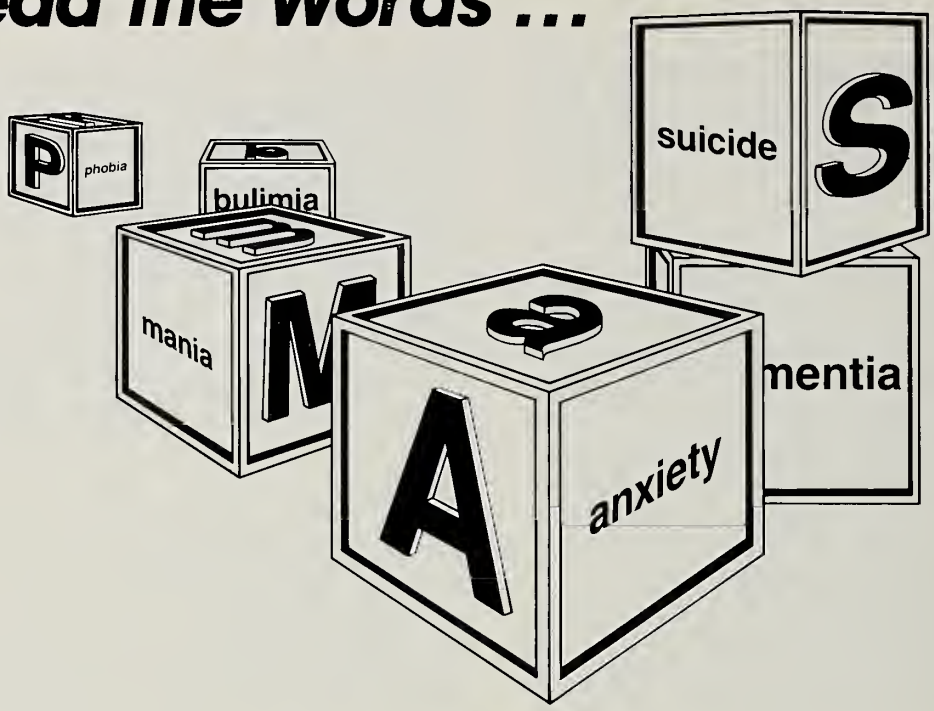

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AEROBIC EXERCISE IN THE MANAGEMENT OF RHEUMATIC DISEASES

Russell J. Labowitz, M.D.
Jayne Challman, M.S.
Scott Palmeri, R.P.T.

Introduction

Therapeutic exercise has been defined as "the prescription of bodily movement to correct an impairment, to improve musculoskeletal function, or to maintain a state of well-being."[1] Exercise training has been shown to be beneficial in rehabilitating patients with chronic conditions including cardiac diseases,[2] hypertension,[3,4] obesity,[5] obstructive lung disease,[6,7] and rheumatoid arthritis.[8,9] Chronic illness causes a deconditioned state, consisting of muscle atony, weakness, fatigue, and reduced cardiovascular endurance. Loss of physical conditioning can be as incapacitating as the primary symptoms of the disease. This problem is paramount in the rheumatic diseases, particularly rheumatoid arthritis (RA), and systemic lupus erythematosus (SLE), where the pathology directly affects the muscles, joints, and connective tissue and causes systemic effects as well. The resulting inactivity, caused by the effects of the disease, can further complicate and worsen the patient's condition.

Aerobic exercises have been recently recognized as one of the mainstays of treatment in fibromyalgia. However, for a long time exercise therapy in RA has not been vigorous, emphasizing instead rest and range of motion exercises. This may be appropriate for acute flare-ups of RA, but recent evidence suggests that a more aggressive approach to exercise, particularly in subacute or chronic RA patients, has added benefits to the overall management of patients.[8,9]

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Ms. Challman has a Master's degree in exercise physiology.
Mr. Palmeri is a registered physical therapist.

Patients with rheumatic diseases, particularly RA, demonstrate a low level of physical performance when measured by aerobic capacity.[10] Regular conditioning exercise can improve their aerobic capacity, functional status, and quality of life without harmful effects on their joints.[11]

Program

We have evaluated an uncontrolled study, judging the effects of a physical reconditioning program on several different rheumatic disease patients. We chose a physical therapy setting (Bancroft Physical Therapy) to closely monitor these patients under the supervision of a physical therapist and exercise physiologists.

The Bancroft Monitored Exercise Program was designed to improve the patient's cardiovascular endurance, muscular strength and endurance, flexibility, and overall quality of life. Each patient was to have three exercise sessions per week for 12 weeks, or a total of 36 sessions, ideally with a day of rest between each exercise session. A session typically consisted of a five minute warm-up, a 40 minute aerobic workout, and a 15 minute cool-down. The warm-up and cool-down components of each exercise session involved a series of therapeutic stretching exercises for the total body.

Each patient was referred by a physician with a diagnosis and prescription for exercise therapy. After a thorough history was obtained from the patient including concurrent medical problems, medications, and a subjective assessment by the patient of personal functional capacity, objective measurements were taken.

The patient's weight, percentage of body fat, anthropometric measurements, resting heart rate, and blood pressure were recorded. Strength and flexibility were measured by bent knee sit-ups, modified push-ups, squat test, sit and reach, and grip strength. Some patients could not perform all these tests due to their differing physical impairments. Therefore, the testing methods for evaluation had to be individualized just as the exercise program itself was individually modified.

A submaximal treadmill test or cycle ergometer test was used to measure cardiovascular endurance. The submaximal treadmill test was performed using a modified Naughton protocol, chosen because it was most suitable for the patient population. A cycle ergometer test was used according to the patient's weight and activity level. Percentage of body fat was calculated by using skinfold measurements at four anatomical sites. The chest, waist, hips, thigh, calf, and upper arm were selected for anthropometric measurement sites. Modified push-ups against a wall or table were used depending on the patient's ability. Sit and reach is a standard measurement of trunk flexibility.

Aerobic exercise was accomplished using a treadmill at various speeds and inclinations, a bicycle ergometer, a rowing machine, and an upper body ergometer. Muscular strengthening was accomplished by using Cybex II isokinetic exercises, wrist/ankle weights of two to five pounds, and mild progressive resistive exercises. An exercise that uses large muscle groups, can be maintained for a prolonged period, and is rhythmical and aerobic is best suited for this type of program.[12] Walking, bicycling, and rowing are good examples.

Based on this thorough evaluation, an individualized exercise program was designed to meet the different needs of each patient. During each exercise session, patients were closely supervised by a physical therapist and exercise physiologists and adjustments to their program were often made. This allowed each patient to exercise to fullest potential, and also to minimize risk of injury or aggravation of underlying disease. In this manner, any patient, regardless of disease or impairment, could enter the program and proceed at an individual pace under the guidance of trained professionals.

Midway through the program, another evaluation was performed and sent to the referring physician, and further adjustments were made by both therapist and physician. The final evaluation was performed at the end of the program. Objective testing was completed and patients were given a questionnaire to assess their subjective improvements.

Patient Selection

Patients with various rheumatic disorders who complained of either fatigue, lack of endurance, or subjective weakness participated in the Bancroft Monitored Exercise Program. All patients were on stable medical regimens and no major changes in drug treatment were made during the study. Although the program was designed for 36 sessions to be completed over a 12 week period, some patients were unable to complete the program in the allotted time. A total of 50 patients completed the program in 20 weeks or less. Their ages ranged from 26-73 years, with a mean of 51 years. There were 43 women and seven men. Nineteen patients had definite or classic RA,[13] American Rheumatism Association functional class II,[14] eleven patients had osteoarthritis (OA), five patients had fibromyalgia (fibromyositis), five patients had connective tissue disorders, and five had various other rheumatic disorders.

Results

Of the patients who completed the study, 50 did so in 20 weeks or less. Twenty-six percent of the patients completed the exercise program in 12 weeks, 48% in 13-15 weeks, and 26% finished in 16-20 weeks. There was no association between diagnosis and time of completion. The main reasons for patients not completing the program in the specified time were multifactorial, but primarily had to do with concurrent illness, employment conflicts, personal reasons, etc. However, there was a significant relationship between time of completion and test results. All patients who exercised an average of two sessions per week showed some improvement, but the patients who exercised three sessions per week obtained the maximum improvement.

Upon completion of the program, patients were given a final evaluation. The final results were then compared to the initial evaluation to determine the patient's progress. Over 90% of the patients tested improved their strength and muscular endurance in the number of sit-ups and

push-ups performed. These patients also increased the duration of the squat test. Ninety-two percent of the patient group improved their flexibility as measured by the sit and reach test.

As a side benefit 77% of the patients lost weight, averaging a loss of 8.5 pounds (several patients were on calorie restricted diets as well). Several patients lost 20-40 pounds. Seventy-two percent decreased their percentage of body fat, averaging a 2.8% loss. It is of interest that of the remaining 23% of patients whose weight either remained unchanged or increased, 15% actually lost body fat.

The resting heart rate decreased in 50% of the patient group. A significant percentage (25%) of the patients that showed no change in their resting heart rate were on cardiac drugs that slowed their heart rate. No significant decrease in blood pressure was observed. Every patient had improved cardiovascular endurance. This was demonstrated by improved performance in the treadmill test and bicycle ergometer.

The patients answered subjective questions about their activity level and health status at the initial and final evaluations. The majority of RA patients reported a decreased pain level but no significant change in the quantity of analgesics used per day. All RA patients reported increased endurance, strength, and flexibility, and overall improvement in their quality of life by decreasing their level of fatigue and improving their productivity. The OA group reported no significant changes in their level of pain, but all patients related increased endurance, strength, and flexibility, and an improved quality of life. The patients with fibromyalgia and connective tissue disorders reported decreased pain, some even reducing their analgesic requirements. All patients in these groups increased their endurance, strength, and flexibility, resulting in a higher energy level. The remaining five patients with various rheumatic disorders (ankylosing spondylitis, one; chronic low back syndrome, two; Reiter's disease, one; and the arthritis associated with chronic active hepatitis, one) all reported improvements in endurance, strength, and flexibility.

Study participants uniformly felt the program was beneficial to them. They felt more confident and learned proper methods of exercise. It was also observed that patients who exercised less than 2.5 sessions per week did not consistently show the same level of improvement as the other patients.

At the conclusion of the program, each patient was encouraged to continue exercising and was given an exercise prescription so that they could continue exercising at home. They were to return in six weeks to be retested and if necessary, adjustments were made in their home program.

Conclusion

Patients with rheumatic diseases can benefit from monitored, individualized aerobic exercise programs. In general, these patients are somewhat reluctant to exercise and usually are not motivated, particularly since many of them already complain of extreme fatigue and lack of stamina. The fear of injury or aggravation of their underlying disease is also of major concern to them. To overcome these obstacles and then to take on the challenge of individualizing exercise programs for these patients takes a team effort. These patients may have several physical impairments that require frequent modifications of the program along with adaptations to the exercise equipment so they can effectively exercise. Often the attending physician, rheumatologist, and cardiologist have to work with a team of physical therapists and exercise physiologists to formulate the most effective and safest exercise program. However, once they become motivated and overcome their fears and anxieties, patients can be shown the proper way to exercise and can achieve the same benefits as a healthy population. Patients with other chronic diseases have been shown to benefit from active exercise programs similar to the Bancroft Monitored Exercise Program.

All the patients completing the program reported improvement in their quality of life. Although this parameter is somewhat subjective, its importance cannot be underrated in patients with chronic diseases. Concomitant depression may also improve in an aerobic exercise program.

Weight reduction was achieved by a majority of the patients. This is an important aspect of treatment, particularly in patients with problems involving weight bearing joints. Nutritional counseling combined with exercise has been shown to be an affective method of weight reduction. In the program, some of the patients met

with a nutritionist once a week.

We believe that patients with a chronic disease and/or physical impairments such as chronic arthritis or low back pain, who have been locked out of most exercise programs due to their physical limitations, can participate and benefit from carefully monitored exercise programs. Although our study is small in numbers and uncontrolled, it does confirm some observations of previous studies.[8-11] If the exercise program is properly designed for the individual patient, there is no increased risk of injury or aggravation of symptoms. The program can benefit patients with rheumatic diseases both subjectively in their global assessment, and objectively by increasing their muscular strength and endurance, cardiovascular endurance, and flexibility. Ultimately these improvements and benefits will allow patients with rheumatic diseases to overcome a major disability by increasing their stamina and reducing their fatigue.

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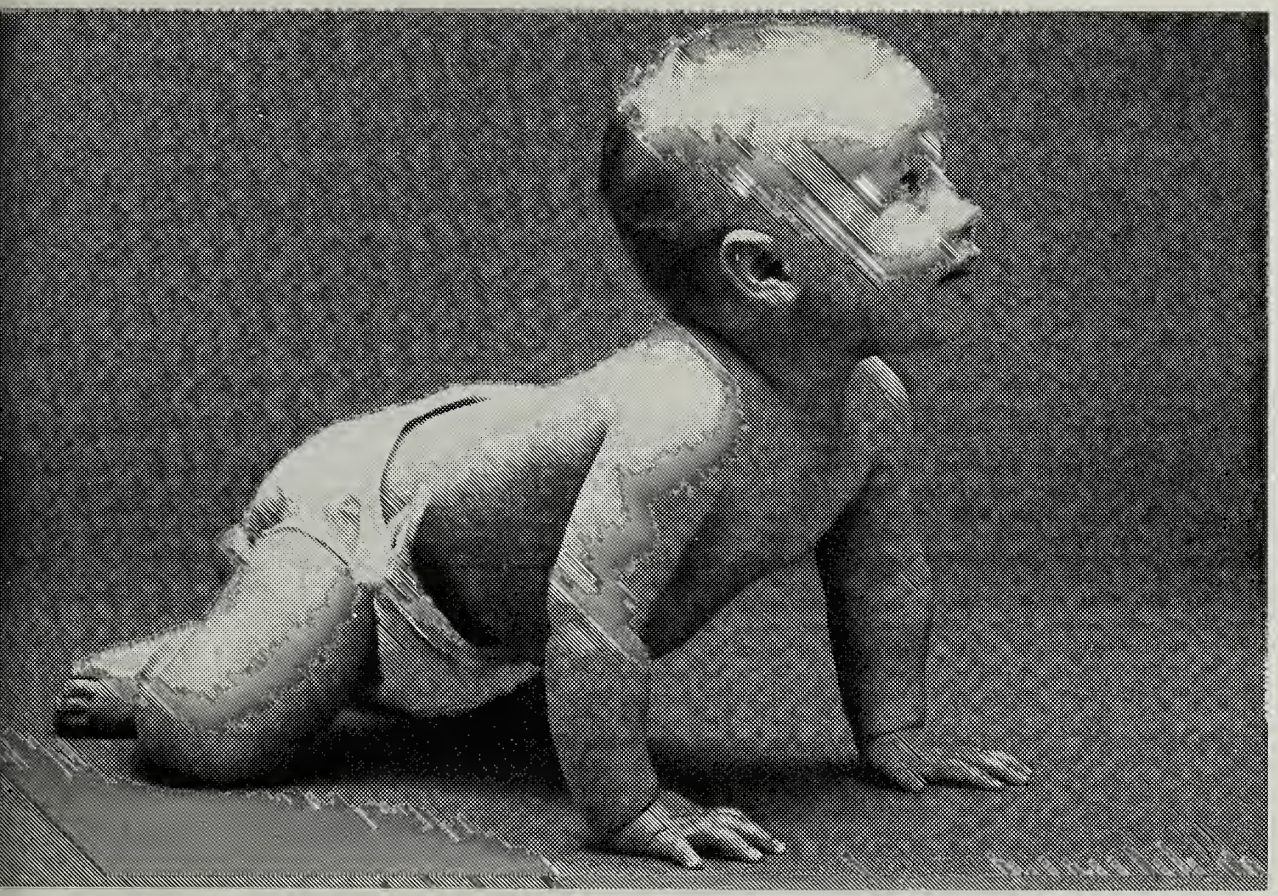

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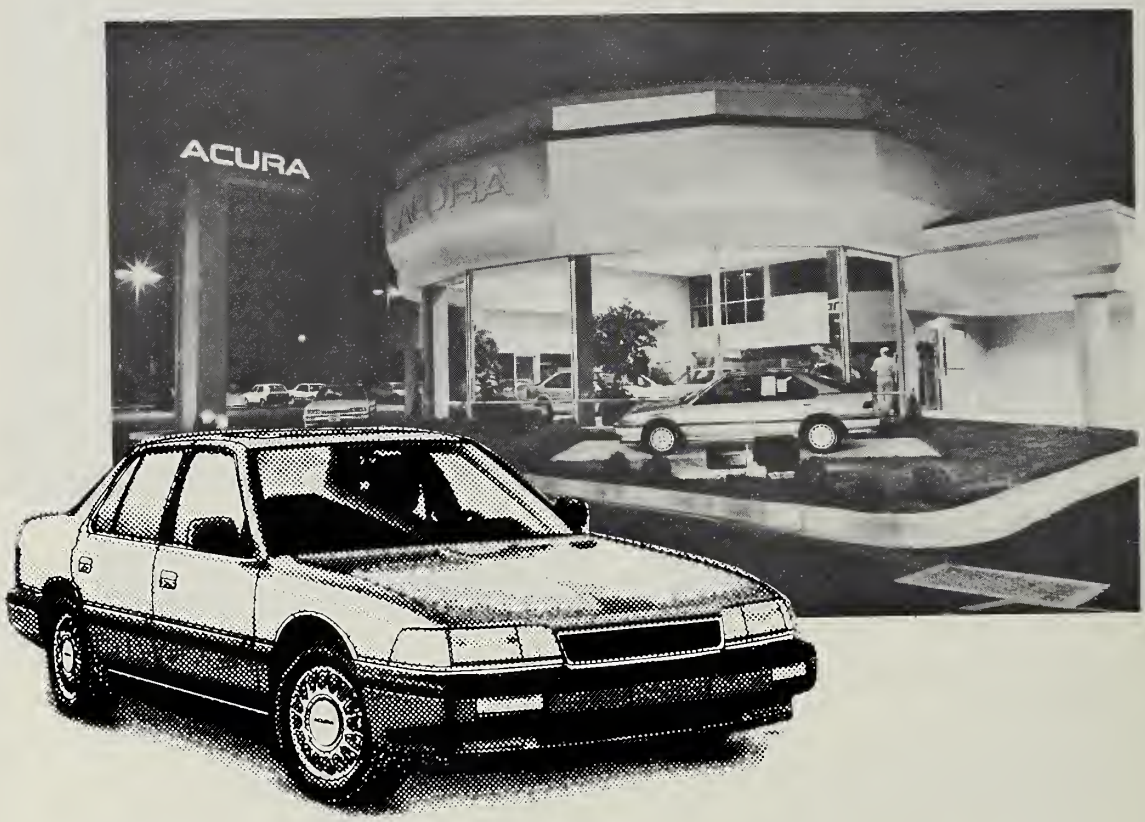

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FROM COMPUTER MODELING TO FDA APPROVAL: RESEARCH STRATEGY FOR THE DISCOVERY OF NEW ANTI-ARTHRITIC DRUGS

Neil R. Ackerman, Ph.D.

Introduction

A large number of therapeutic agents are currently available to treat patients with rheumatoid arthritis (RA). These can conveniently be divided into three categories:

1. Nonsteroidal antiinflammatory drugs or NSAIDs;
2. Second line or slow onset antirheumatics; and
3. Third line or immune suppressants.

Each class has a series of attributes which makes it attractive to a select set of patients; each class likewise has drawbacks. In the first part of this presentation, the major features of the first two classes will be described and their major deficiencies outlined. This will lead into the second section, that of patient need and the strategy for the development of better antiarthritic drugs.

Currently Used NSAIDs and Second Line Drugs

A large number of nonsteroidal antiinflammatory drugs are currently available, with the most widely used being naproxen (Naprosyn, Syntex), piroxicam (Feldene, Pfizer), and sulindac (Clinoril,Merck Sharp & Dohme). All have antiinflammatory and analgesic activity but suffer from two major drawbacks: they do not influence the course of the disease, and they have significant side effects. Their activity is considered palliative, in that the progression of the joint changes, as evaluated radiologically, does not appear to be influenced by the drugs. Of equal concern, a significant number of patients experience gastrointestinal upset with serious ulceration of the stomach and small intestine reported. Renal toxicity, a second major side effect especially in elderly patients, is of growing concern among physicians.

Among the second line or slow onset antirheumatics the major agents are gold (gold sodium thiomalate or Ridaura, Smith Kline & French), penicillamine (Cuprimine, Merck Sharp & Dohme), hydroxychloroquine (Plaquenil, Winthrop-Breon), and sulfasalazine (Azulfidine, Pharmacia). They differ significantly from each other in regards to their mechanism of action. Gold, for example, has been reported to influence macrophage function, while penicillamine affects B lymphocytes. All suffer from having long term onset of action, and little evidence exists for their being truly disease-modifying. In a critical review

Dr. Ackerman is Research Manager of the Immunopharmacology Department of the Medical Products Department at E.I. duPont de Nemours in Wilmington.

of 60 published studies purported to evaluate disease remission, only 17 studies included radiographic assessment of treated and control groups. Of the second line therapies, only parenteral gold was shown to have some activity as a disease modifier. These drugs all suffer from significant side effects with gastrointestinal problems and blood dyscrasias being most important. In conclusion for this section, major patient needs appear to be safer NSAIDs and effective disease modifiers.

Strategies for New Drug Discovery

Two different approaches have been used within the pharmaceutical industry to identify drugs which may be either safer NSAIDs or disease modifiers. In the first case, a relatively traditional approach was taken, ie, various agents were compared in animal model systems for both efficacy and toxicity. The model for efficacy is termed the adjuvant arthritic rat. In this model, rats are injected with an immunologic stimulant, complete Freund's adjuvant, which induces alterations in the rat hindpaw similar in some ways to that seen in patients with RA. The paw is swollen, becomes tender, and ultimately undergoes destruction of the cartilage and bone. Many of these events can be blocked with NSAIDs. A second model is available for measuring the side effects of stomach ulceration. Rats treated with NSAIDs suffer from ulcer formation. Doses of various drugs can be compared for their ulcer inducing activity.

During the course of our program the medicinal chemists within the group began synthesizing a series of drugs termed diaryl heterocycles. One of the most interesting of these is S-6907. It has been compared with a large number of NSAIDs in the animal models described above. It had an apparent safety margin in excess of 2000; this means the rats tolerated 2000 times the effective dose without developing gastrointestinal lesions. Most routinely used NSAIDs have safety margins of 1-40, indicating that S-6907 has a high degree of safety.

The second need mentioned above is that of developing disease modifiers. To achieve this goal, we are using computer modeling for the drug design process. To understand the rationale behind this approach, the biochemistry of the inflammatory response needs to be presented. The major mediators of the inflammatory response are the prostglandins which are responsible for the pain and swelling seen in arthritic patients. A second class of mediators, leukotrienes, contribute to the inflammatory cell infiltration seen at the disease site. These cells are thought to be responsible for some of the joint destructive events. The formation of the first class of mediators is blocked by the NSAIDs. Both classes of mediators are derived from a common precursor, arachidonic acid. This is released from a variety of cell membranes by the enzyme phospholipase A_2. If a drug could block this enzyme, it could potentially halt the entire inflammatory reaction, including the joint destructive events, and thereby function as a disease modifier.

The strategy we have developed to detect a phospholipase inhibitor is:

computer model the enzyme and design inhibitors

↓

test the inhibitor against the enzyme

↓

test the inhibitor in cellular models for its ability to block arachidonic acid release

↓

test the inhibitor in an animal model of inflammation

Few compounds had been previously described which can actually block this enzyme. One member of our group, Dr. William Ripka, used computer graphics to design a novel series of PLA_2 inhibitors. These were 100-fold more potent than anything previously described in the literature. A few of these compounds have also been found effective in cellular model systems. We have not designed any PLA_2 inhibitors which function as effective antiinflammatories. Even when we have such a compound, a great deal of time must be used to obtain Food and Drug Administration approval. At the present time, ten years is usually required to go from drug discovery to the marketplace. I expect we will be seeing some incremental advances over currently used drugs being made in the next few years. The blockbuster of disease modifiers is probably not around the corner. However, by conducting the types of research we and many other companies are pursuing, such drugs will be discovered and ultimately be available to the patient.

View Box

COMMON ARTHRITIC MANIFESTATIONS

Richard Wallace, M.D.
Paul McCready, M.D.

Case 1

Note the generalized periarticular osteoporosis with marginal erosions at the third metacarpal-phalangeal (MCP) and proximal interphalangeal (PIP) joints. There is uniform joint space narrowing at the third MCP joint.

What is your diagnosis?

Dr. Wallace is a radiologist practicing in Wilmington.
Dr. McCready is a radiologist practicing in Wilmington.

Rheumatoid arthritis

Diagnostic features of rheumatoid arthritis include symmetric joint involvement bilaterally, periarticular osteoporosis, symmetric joint space narrowing, and marginal erosions.[1,2] Characteristically, the ulnar styloid process and second and third MCP joints are involved early. Typical distribution is the MCP, PIP, and carpal joints.

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1. Resnick D, Niwayama G. Diagnosis of Bone and Joint Disorders, Vols 2 & 3. 954-1067, 1171-1198, 1364-1479, 1618-1671.
2. Edeiken J. Roentgen Diagnosis of Diseases of Bone, Vol 1. 414-678.

Case 2

There is a large eroding tophus with overhanging edges at the fifth distal interphalangeal joint (DIP), with multiple erosions of the carpal bones and at the carpal-metacarpal joints.

What is your diagnosis?

Gout

Gout typically shows a random distribution in the hand, multiple erosions without joint space narrowing, or periarticular osteoporosis, soft tissue swelling due to tophi, and a periosteal attempt at repair resulting in an overhanging edge appearance. The erosions may occur at a distance from the joint.

Case 3

There are extensive erosive changes at the PIP and DIP joints of the second digit with bony ankylosis and whittling of bone ends at the MCP joints with pencil-and-cup deformity. Also note the erosion of the distal navicular with bony proliferative changes.

What is your diagnosis?

Psoriatric arthritis

Features of this form of arthritis include periarticular osteoporosis, erosions, ankylosis, and fluffy bony proliferation adjacent to erosions and at tendon and ligamentous insertions. The DIP joints are typically involved and, as in the case presented, a single digit may be extensively involved.

Case 4

Note the joint space narrowing, bony sclerosis, and hypertrophic spurring without periarticular osteoporosis seen in the DIP, PIP, and first carpal-metacarpal joints.

What is your diagnosis?

Osteoarthritis

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Medical Ethics

INFORMED CONSENT

In most discussions about informed consent, the difficulty of truly informing the medically unsophisticated about technical risks is overlooked. Too little is known about the pros and cons of informed consent. It would be nice if the Kennedy Institute, with its professed interest in ethical problems, would take on that challenge. This could lead to better ways of assuring that those patients who want to be informed have their concerns addressed in understandable language.

Many of us in oncology have learned that what we thought was a fully explained recommendation to a patient was not understood at all until a skilled oncology nurse spent considerable additional time reviewing the situation with the patient and frequently the patient's family. Sometimes this may be a matter of repetition, other times a different choice of words and examples, or perhaps because the patient and/or family is willing to ask the nurse questions they are hesitant to ask the physician, or because the nurse has more credibility for one reason or another. Often all factors play a part in helping people to understand.

Some patients do not want an explanation. They trust their physician and will do what he suggests, and become upset when given too many options. They want advice. We as physicians could profit from experience and research to help us understand what the patient wants and to help us learn how to respond in ways that are understandable. It is obvious that some explanations are almost impossible for those without a medical school background, and for some of today's advanced technology, even that is not enough.

Theoretical discussions of informed consent concerns by professional ethicists often miss the point. The lack of bedside experience is often obvious. Even discussions of measures to affect the quality of life often lack appreciation of different values in varying situations. A paraplegic who has adjusted to his situation has far different expectations than those of us without that handicap. I have been singularly unsuccessful in trying to persuade non-medical critics of the informed consent process for research protocols to understand that they should be more concerned about patients for whom an informed consent is not required. This is especially so in situations where the physician does not provide a patient eligible for a research protocol the option of participating, especially when so-called standard treatment does not have a high likelihood of success. Because women have frequently not been told of the options available in the management of breast cancer, legislators in several states have mandated that physicians provide such a service. It is hoped that the Delaware legislature will not feel the need to initiate such a requirement. By now we hope most patients are being told of their options and that Delaware physicians are trying to provide their patients with alternative options, and, when indicated, second opinions as part of their therapeutic advice.

There is good evidence that the detailed explanations given to patients on research studies have been associated with few, if any, malpractice actions. Therefore, not only is it ethically desirable to encourage full patient understanding of proposed treatments, but it probably may be one of the best ways to avoid malpractice actions.

Robert W. Frelick, M.D.
Chairman
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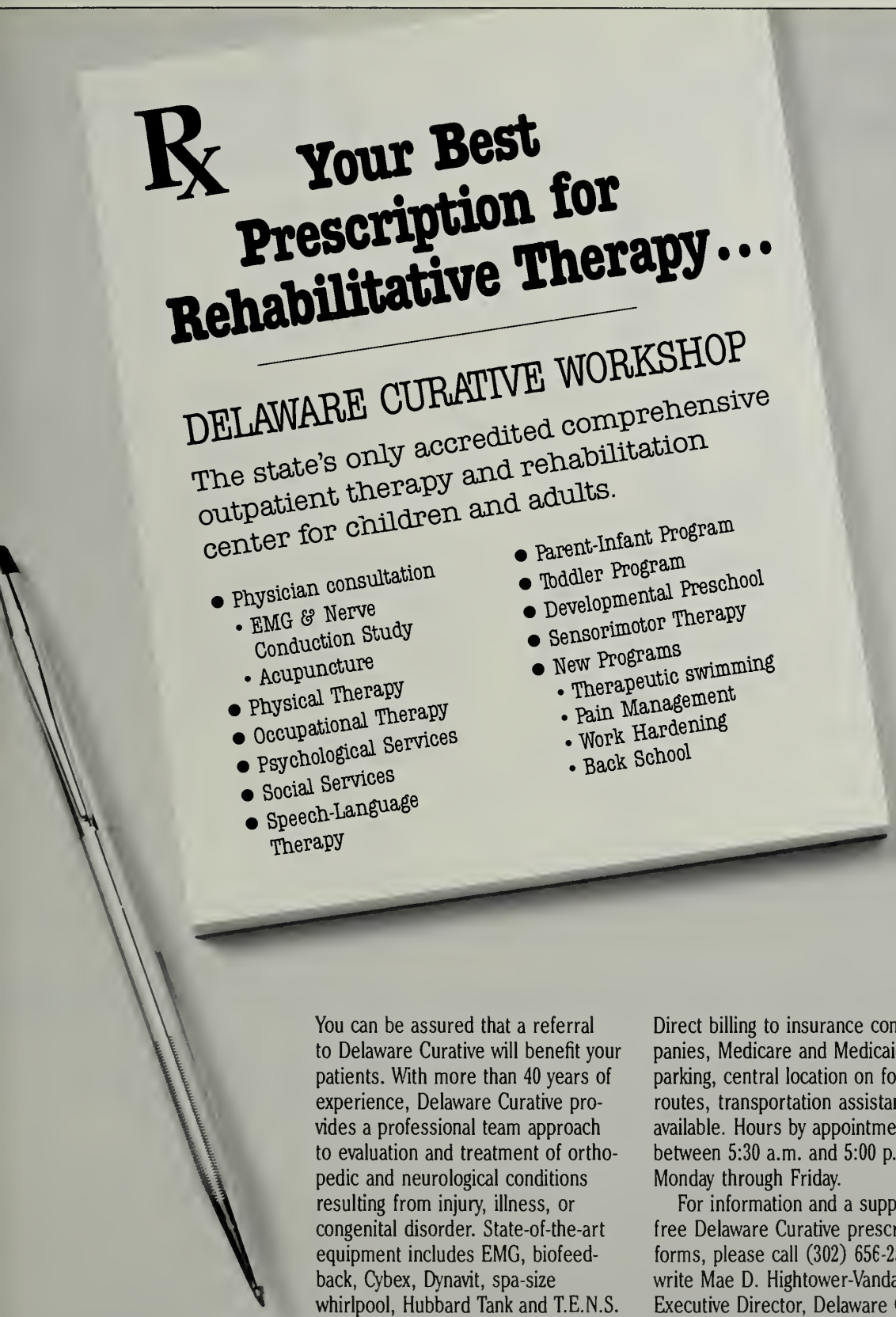

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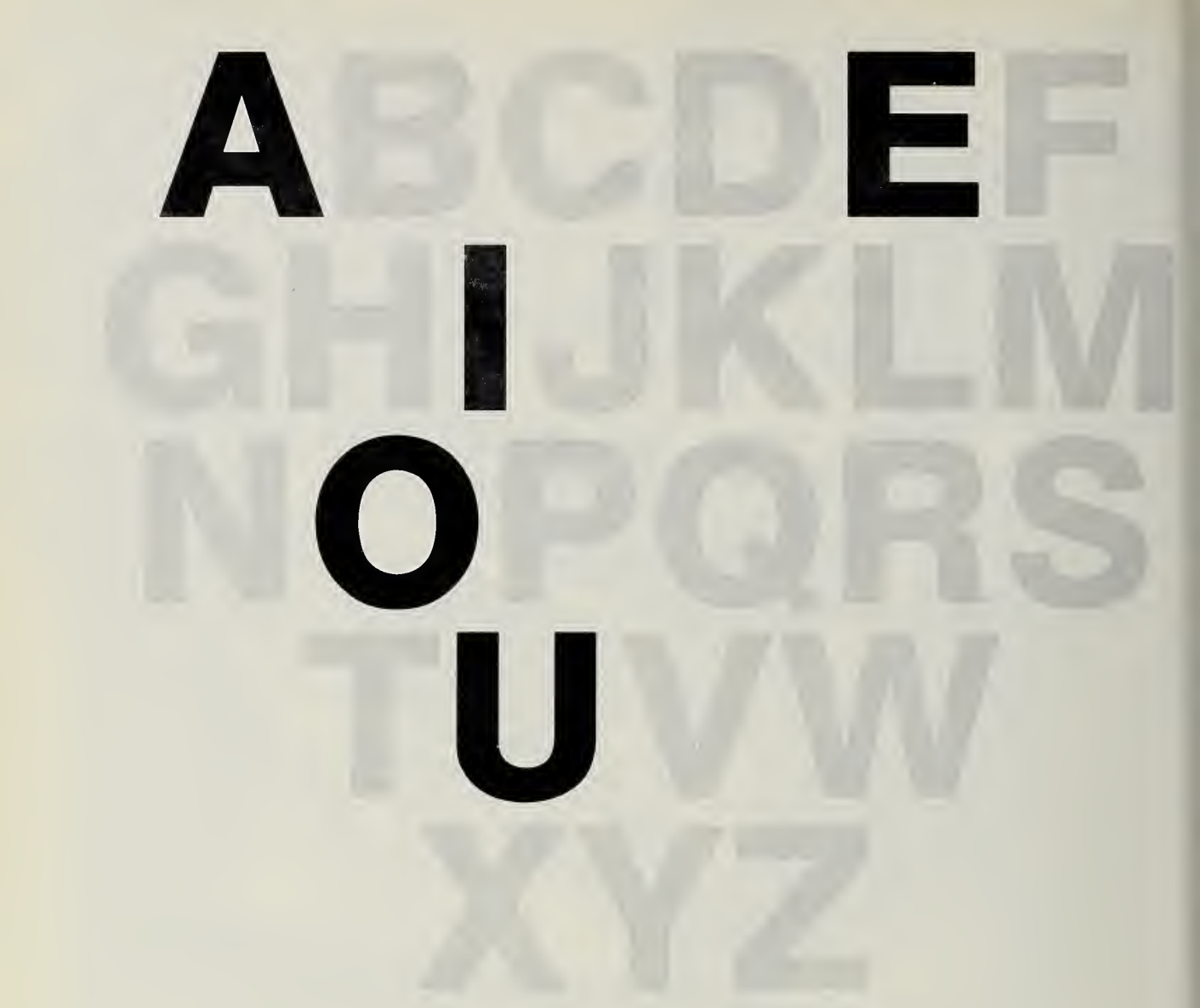

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Editorials

SPOTLIGHT ON THE GUEST EDITOR

Dr. James H. Newman has lived and practiced consultative rheumatology in Wilmington since 1980. He received his Bachelor of Arts and Medical degrees from Cornell University prior to an internal medicine residency at the Hospital of the University of Pennsylvania. His postdoctoral fellowship in rheumatology at Yale University was highlighted by clinical investigation involving Lyme disease. He is board certified in Internal Medicine and Rheumatology. In addition to private practice, he maintains an active teaching role at the Medical Center of Delaware and is on the clinical faculty of Jefferson Medical College and the University of Pennsylvania School of Medicine. A fellow of the American College of Physicians, Dr. Newman has authored or coauthored 21 articles in the medical literature, including the current issue of the *Delaware Medical Journal*.

He is most proud of his two sons, Michael (age 8) and Craig (age 4), and of Leslie, his wife, without whose continuing support he would be lost.

INTRODUCTION

This issue of the *Delaware Medical Journal* is devoted to topics in rheumatology. It is based on the 1988 Rheumatology Update, a yearly symposium organized by the Delaware Chapter of the Arthritis Foundation as an educational service to Delaware physicians. The goal of the Update is to provide timely reviews of important issues in the field of arthritis research and treatment. It has been a very successful program with many physicians attending over the past eight years.

I would like to gratefully acknowledge the authors who contributed to this issue. I would also like to thank the *New York Times* for allowing us to reprint Dr. Stone's essay, which I found moving and personally quite meaningful. I hope my colleagues enjoy the November *Journal*.

James H. Newman, M.D.

OMEGA-3 FATTY ACIDS IN RHEUMATOID ARTHRITIS

Omega-3 fatty acids have received worldwide publicity for their potential role in the amelioration of vascular disease. Attention was first focused on these marine lipids by Danish researchers who found that Greenland Eskimos had an extremely low incidence of coronary artery disease in spite of a diet high in fat and cholesterol. They also found that the Eskimo diet is rich in eicosapentaenoic acid (EPA) and docoashexaenoic acid (DHA) from a diet derived entirely by eating fish and blubber.

These fatty acids have a unique structure in which the first double-band is found three carbon atoms removed from the terminal methyl group (thus the name omega-3), instead of six carbon atoms away, as in the fatty acids derived from plants and animals from the terrestrial part of the globe (the omega-6 fatty acids).

The fatty acid structure is important, since these lipids are incorporated into cellular membranes throughout the body where they serve as some of the basic building blocks for very important biological reactions. Some of these reactions are intimately involved with the vascular propensity to form (or not to form) a clot. Others affect the actual level of circulating VLDL (and to a

lesser extent LDL). All the reactions associated with ingestion of omega-3 are associated with a net decrease in the biological progression of artherosclerosis and are consistent with the observed benefits in epidemiological and laboratory studies.

Some of the other changes in biological systems after ingestion of omega-3 involve inflammation and the immune response. Omega-3 fatty acids can serve as an alternate substrate for inflammatory products normally derived from arachidonic acid (and the omega-6 fatty acids). The omega-3s compete with the omega-6s and partially inhibit the production of some very potent inflammatory mediators in the leukotriene and prostaglandin families. Studies in humans have demonstrated a significant fall in leukotriene B4, a potent inflammatory substance derived from neutrophils after six weeks of fish oil consumption. Such effects might contribute to the improvement observed in some animal models of inflammatory disease.

There is thus a fair amount of theoretical evidence to suggest that fish oil fatty acid dietary supplements might benefit patients with rheumatoid arthritis. Expanding on a pilot study performed at Albany Medical College which demonstrated some possible beneficial effects on disease activity in rheumatoid arthritis, we undertook a blinded placebo-controlled crossover investigation of fish oil fatty acid supplementation. The design allowed us to compare patients with active disease with themselves while on either fish oil or an identical-appearing placebo capsule. Background diet and medications for rheumatoid arthritis were maintained without change during the 36 week duration of the study. Clinical disease variables were monitored at seven week intervals with simultaneous monitoring of neutrophil derived leukotriene B4.

The results of this study indicated statistically significant differences in certain measures of rheumatoid disease activity (the number of tender joints on exam, and the interval to the first onset of fatigue) which favored fish oil consumption. That is, when patients were compared with themselves during equivalent periods of taking either omega-3 fatty acids or placebo supplements, they had less disease activity while taking the fish oil. Indeed, all clinical parameters measured favored the period when patients consumed fish oil, even though only two of 11 measures achieved statistical evidence. Improvement also correlated in a highly statistically signifi-

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Pierre L. LeRoy, M.D., F.A.C.S., C.C.E., Medical Director

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cant way with decreases in neutrophil leukotriene B4 observed while patients ingested the fish oil supplements.

Thus, dietary manipulation can affect the clinical manifestations of a chronic inflammatory disease. Yet many unanswered questions remain, which assure that investigators will be busy in this area for years to come. Although neutrophil leukotriene B4 does decrease with omega-3 consumption, most investigators in the field feel that there must be additional immune-mediated events which could be influenced by altered biological membranes. These alterations could perhaps play a larger role in the benefits seen in rheumatoid arthritis patients than those ascribed to decreased inflammation associated with lower levels of leukotriene B4.

Other unsettled issues include the optimal amount of omega-3 supplementation and whether or not benefits seen in short term studies will be sustained for longer periods of time. Some of these basic questions will need to be answered before we can assign omega-3 dietary supplementation to its proper role in the treatment of rheumatoid arthritis.

Joel M. Kremer, M.D.

Dr. Kremer is Associate Professor of Medicine, Division of Rheumatology, Albany Medical College.

A HISTORY OF THE ARTHRITIS FOUNDATION, DELAWARE CHAPTER

The Delaware Chapter received its charter from the National Arthritis and Rheumatism Foundation on February 10, 1960. It had been formed at a meeting of public spirited citizens including Mr. Ellason Downs, Mrs. Elizabeth Grasselli, and Mrs. Eloise Porter. Mr. Downs became president and Dr. W. Thomas Hall served as the chairman of the Medical and Scientific Committee. At first the workers were all volunteers, but in 1972 Mrs. Vivian Davis was hired as a part time executive director.

The Chapter office was located in the Academy of Medicine building but moved to the Home of Merciful Rest in 1967. Two subsequent relocations now find the office at 222 Philadelphia Pike. Mrs. Anne Clendaniel became the first full time executive director. She began work "in an attic room where the phone never rang." The chapter was fully active and flourishing by the time she retired more than ten years later. She was followed by Mary Kopcza and by the current executive director, Peter E. Corrado.

The current chapter board includes Mrs. Jean H. Maury, Chairman; Wendell R. O'Neill, President; Dr. Martin J. Glynn, Medical Vice Presi-

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dent, and Chairman of the Medical and Scientific Committee. Others on the board include members of the medical community as well as laymen, attorneys, and interested arthritis patients and their families.

Over the years, the numerous programs of the Delaware Chapter have stressed patient and physician education. From the beginning, literature and patient information have been made available from the National Foundation. In addition, an arthritis newsletter has been published by the Chapter on a regular basis for many years in order to provide its readers with useful information about arthritis and the activities of the Chapter.

Early physician educational efforts included funding fellowships in Rheumatology for Dr. Russell J. Labowitz at the University of Pennsylvania in 1969, and for Dr. Christopher J. Donoho, Jr., at Jefferson Medical College in 1972.

For a number of years, the Arthritis Clinic at the Delaware Division was supported in part by the Chapter, as was the Georgetown Rehabilitation Center. Until the arrival of a full time rheumatologist in Milford, the Chapter subsidized Arthritis Consultation "clinics" at the Milford Hospital and at the Nanticoke Hospital. Both hospitals were visited on a regular basis by rheumatologists from New Castle County.

The Chapter has developed self-help courses which teach patients how to live within the limits their arthritis imposes. They give tremendous support to the patients and their families. Several arthritis clubs have also been established by the chapter for patients and families to discuss problems with expert speakers and with one another in regularly scheduled sessions. Arthritis forums have been held throughout the state. In these, rheumatologists, orthopedic surgeons, and other health care professionals speak to the public and answer questions on arthritis topics.

The Rheumatology Update has become an important physician and allied health professional educational tool. Under the direction of the Medical and Scientific Committee, it has improved yearly and helps to keep the medical communi-

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ty abreast of the latest advances in the field. Held yearly, attendance continues to rise, and its future looks bright.

In 1988, the Delaware Chapter finds itself expanding its programs while working to involve the community in helping to financially support itself and the National Foundation. Self-help courses, the patient loan closet with arthritis aids, and distribution of literature to patients, physician offices, clinics among other health related activities are all important Chapter functions at this time. Future growth plans include the addition of an office in Southern Delaware, which when staffed will allow better outreach in Kent and Sussex Counties; improved and more accessible office space in Wilmington; and continued support of research, patient services, and education.

From its start as a small volunteer organization, through its sometimes troubled middle years, to its present position as advocate for arthritis patients, the Delaware Chapter of the Arthritis Foundation faces the future with optimism and hope. Its mission is, "help and hope through services, education and research."

Christopher R. Donoho, Jr., M.D.

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DIGITORUM NODI: LITTLE HARD KNOBS

The Heberden Society, a British society for the study of arthritic diseases and related conditions is quartered in the Royal College of Physicians building in London. The only known portrait of Dr. William Heberden stands outside its office. The society was so named in honor of Heberden's original description of the degenerative changes of osteoarthritis of the distal interphalangeal joints. Although he did not know what they represented, Heberden described them quite clearly.

A quintessential 18th century physician whose long life (1710-1801) spanned almost the entire century, Heberden's contributions to the literature of medicine were often in the form of queries about things he did not understand. His clinical descriptions were, however, so succinct they even now in an era when eponyms have become distinctly unfashionable and in many journals no longer personalized by the apostrophe, the expression "Heberden's nodes" still endures, and the pain of myocardial ischemia is still called by the name he gave it, angina pectoris.

The original description of the knobby bumps was in Chapter 28 of his major opus *Commentaries on the History and Cure of Diseases*, published the year after his death. Here reprinted, it contains only 80 words.

> What are these little hard knobs, about the size of a small pea, which are frequently seen upon the fingers, particularly a little below the top, near the joint? They have no connection with the gout, being found in persons who never had it; they continue for life; and being hardly ever attended by pain, or disposed to become sores, are rather unsightly, than inconvenient, though they must be of some little hindrance to the free use of the fingers.

We believe Dr. Heberden, one of the first rheumatolgists, would have enjoyed this rheumatologic issue of *Delaware Medical Journal.*

Bernadine Z. Paulshock, M.D.

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Letter to the Editor

MENTAL ILLNESS AWARENESS

To the Editor:

"Let's Talk About Mental Illness" was the theme for Mental Illness Awareness Week this year. It is the advice given by thousands of mental health professionals this year during a nationwide effort to stimulate the public to speak openly about the realities of mental illness. The theme was stressed during the Fifth Annual Mental Illness Awareness Week, held October 2-8 this year.

Mental illness is one of the most serious of our nation's public health problems, affecting one in five adults, and costing millions of dollars each year in health care expenses and lost productivity. Mental illness also constitutes one of the most misunderstood and feared groups of illnesses. As a result, many people who could benefit from treatment--four out of five--do not receive it.

One reason is stigma. To overcome stigma, to take these illnesses out of the closet, we have to talk about them--what they are, how they feel, how they are treated, the chances of recovery, and the hope of a cure through research.

During Mental Health Awareness Week this past October, the Psychiatric Society of Delaware, the local branch of the American Psychiatry Association, joined psychiatrists and mental health specialists across the country in talking about mental illness. We sponsored public lectures, appeared on radio and television, contributed to articles about mental illness in newspapers and magazines, and visited schools and churches.

As part of the 1988 Mental Health Awareness Week campaign, materials on the "Let's Talk About" theme have been developed for public distribution. These materials, suitable for distribution to your patients, are available by contacting the Psychiatric Society of Delaware, Suite 10B, Trolley Square, Wilmington, Delaware, 19806, or by calling 654-6353.

Robert N. Dumin, M.D.

Dr. Dumin is Chairman of the Public Affairs Committee of the Psychiatric Society of Delaware.

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Deaths

Donald F. Coburn, M.D.

Dr. Donald F. Coburn, a neurosurgeon with a practice in Wilmington, died September 15, 1988. He was 81.

Dr. Coburn graduated from Washington University School of Medicine in St. Louis in 1930. He took his residency at Montreal General Hospital in Canada and Boston City Hospital, Boston, and a fellowship in neurosurgery at Montreal Neurological Institute. In 1938, he started his practice in neurosurgery in Kansas City, Missouri. He was also an associate in Surgery at the University of Kansas Medical Center. He moved to Wilmington in 1979 to open a practice in neurosurgery. He was the Neurological Consultant to the Disability Determinations Service and Vocational Rehabilitation until the time of his death.

He was a member of the American Association of Neurological Surgery, a past vice president of the Academy of Neurological Surgeons, the Society of Neurological Surgeons, Alpha Omega Alpha Honor Medical Society, the American Medical Association, the Medical Society of Delaware, the New Castle County Medical Society, and several medical societies in Kansas and Missouri.

Homer M. Kimmich, M.D.

Dr. Homer M. Kimmich, a former staff member of the Veterans Hospital, Elsmere, died October 29, 1988, of cancer. He was 61.

Dr. Kimmich was formerly the Chief of the Department of Otolaryngology at the VA Hospital when he left to start a private practice in Sunbury, Pennsylvania earlier this year. He had been at the Elsmere hospital since 1980.

He was a 1949 graduate of Haverford University and a 1955 graduate of Temple University School of Medicine. He was a member of the American Medical Association, the American College of Surgeons, the Medical Society of Delaware, and the New Castle County Medical Society.

Lester A. Bronheim, M.D.

Dr. Lester A. Bronheim, of Newtown Square, Pennsylvania, died of cancer September 28, 1988, at the Medical Center of Delaware. He was 56. Dr. Bronheim had a private practice in psychiatry at the Dorset Condominiums. He was on staff at the Medical Center of Delaware, as well as at Rockford Center and Riverside Hospital. Since 1976 he served on the faculty at the University of Pennsylvania, where he was assistant clinical professor in the Department of Psychiatry. Dr. Bronheim formerly was staff psychiatrist at Delaware State Hospital.

Dr. Bronheim graduated from the University of Chicago in 1961 and the medical school at the University of Heidelberg in Germany in 1965. He interned at St. Joseph's Hospital in Yonkers, and did his residency in psychiatry at Kings Park State Hospital, New York School of Psychiatry, and St. Vincent's Hospital, all in New York.

At one time, Dr. Bronheim headed the clinical investigational service, Division of Psychopharmacology at McGill University in Canada. He was also a member of the consulting staff of the Department of Psychiatry at Queen Elizabeth Hospital in Montreal. Between 1970 and 1980, he was involved in psychopharmacology research at Roerig, and was associate director of clinical psychiatric investigations at Wyeth Laboratories.

Dr. Bronheim was a Diplomate of the American Board of Psychiatry and Neurology, and a member of the American Psychiatry Association, the American Medical Association, the Medical Society of Delaware, and the New Castle County Medical Society. He was also secretary of the Psychiatric Society of Delaware.

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- Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.
- Safety and effectiveness have not been determined in pregnancy, lactation, and infants less than one month old. Ceclor penetrates mother's milk. Exercise caution in prescribing for these patients.

Adverse Reactions: (percentage of patients)

Therapy-related adverse reactions are uncommon. Those reported include:
- Gastrointestinal (mostly diarrhea): 2.5%.
- Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment.
- Hypersensitivity reactions (including morbilliform eruptions, pruritus, urticaria, and serum-sickness-like reactions that have included erythema multiforme [rarely, Stevens-Johnson syndrome] and toxic epidermal necrolysis or the above skin manifestations accompanied by arthritis/arthralgia, and frequently, fever): 1.5%; usually subside within a few days after cessation of therapy. Serum-sickness-like reactions have been reported more frequently in children than in adults and have usually occurred during or following a second course of therapy with Ceclor. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.
- Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.
- As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely.
- Rarely, reversible hyperactivity, nervousness, insomnia, confusion, hypertonia, dizziness, and somnolence have been reported.
- Other: eosinophilia, 2%; genital pruritus or vaginitis, less than 1%, and, rarely, thrombocytopenia.

Abnormalities in laboratory results of uncertain etiology
- Slight elevations in hepatic enzymes.
- Transient fluctuations in leukocyte count (especially in infants and children).
- Abnormal urinalysis; elevations in BUN or serum creatinine.
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President's Page

SALVE ATQUE VALE

There is an old Latin proverb that states *salve atque vale*, - hail and farewell. This saying is apropos to the Medical Society of Delaware as we say farewell to our 199th year and hail to our third century of existence.

Could our medical forefathers ever have thought how things would develop when the Medical Society of Delaware was founded in 1776 and incorporated in 1789, second only to New Jersey in terms of longevity. We have grown from 27 physicians who first met in Dover and started the organization to over 1,000 members today.

At the time of the first meeting in 1789, Dr. James Tilton was elected president, and he held that office for 33 years, until 1822. The stated purpose of the society was to assist physicians in the organization and distribution of medical services and care to the citizens of the Delaware state. They had many of the same type of problems we encounter today, but less in severity and scope than some of ours. They were concerned with availability of medical care to people and how these services would be handled. Transportation was a big problem--many house calls were made by primary care physicians--when news of the request reached the physician. Today, transportation of patients to medical care facilities is acutely available at all levels. However limited the levels of skill were in the 18th century, the physician was admired and respected for all that he provided--he hardly worried about medical malpractice, tort reform, or malpractice insurance availability.

Many complex diseases caused great concern among pioneer physicians--but in that vein we are the same today with HIV, cancer, heart disease, etc. However, our levels of expertise and technology have given today's practitioners a correspondingly higher level of anxiety and concern.

Before we close the books on our second century, I must look back over this past year and say special thanks and appreciation to Dr. Martin Cosgrove for the inordinate amount of time he spent solving some very serious problems. The expected increase in medical malpractice insurance premiums for November 30, 1988, caused great concern for Dr. Cosgrove and his insurance committee, and catalyzed a frenzy of activity trying to find a reasonable alternative. We had meetings with PHICO to discuss the reasons for these increases and indeed they seemed logical, but the new rates were unacceptable. Then, there began almost weekly meetings with different approaches to malpractice insurance coverage--including a captive insurance company--a risk retention group--joining with another state medical society to participate in their insurance programs, and finally, being insured by a company other than PHICO, if we could find such a company.

During all this time, Dr. Cosgrove must have put 10-15,000 miles on his car--back and forth from Seaford to Wilmington or Dover. As you all know now, we will have a good medical malpractice program with assured, predictable availability, good risk management programs to keep us aware of pitfalls that tend to entrap physicians, and committees that will listen to our protestations and help us. For this I say thank you Dr. Cosgrove.

The other big problem that was solved during his tenure as president was finding a replacement for someone we all thought--hoped--prayed--would be here forever--our Executive Director--Mrs. Anne Bader. It's tough to replace someone who always was here to help, to answer questions, to keep us out of trouble, to get things done in the Legislature, etc, but Dr. Cosgrove and his committee found Mr. Mark Meister and successfully convinced him that coming to Delaware as our Executive Director would be the high point of his career. Again, thank you, Dr. Cosgrove.

As to this next year--what is there left for me to do? I believe it is going to be a year for anniversary celebrations. Indeed, we have a special memorial session of the House of Delegates set for Saturday, May 13, 1989, in Dover in the State House. Dr. Bill Duncan has promised us colonial transportation--horse and carriage, with cocktails and buffet afterwards at Woodburn. We also plan to have a special edition of the *Delaware Medical Journal* in the spring of 1989, a medical exhibit at the University of Delaware,, and a commemorative pageantry at our annual meeting in November.

On the serious side, we still have concerns with membership, insurance with risk management, and finally, computerization of the Medical Society office and records.

The problems facing our membership are coming from all sides and include the slow, inexorable drift toward socialization and government mandates over medicine, not only in cost control, but also in questions about the quality of medical care with many non-medically trained experts actually questioning how valid our medical judgment is in the management of illness.

The availability, quality, and cost of medical malpractice insurance is always on the agenda for Board of Trustees meetings. I believe you will find that PHICO and CNA will have much greater involvement with all physicians who purchase their insurance than previous insurance companies have shown in Delaware physicians. Risk management conference attendance will be almost mandatory, as evidenced by the CNA provision of reduced rates for attendees, and all insurance companies are going to ask the question, "Why should we sell you insurance?" They are anxious to do business only with physicians who are not risky--this is a sellers market, not a buyers market.

The full computerization of the Medical Society office will streamline our operation. We need to have all physician demographics readily available for updating changes and utilization. With over 1,000 members to service, word-processing, spreadsheet and database management skills are very important.

Finally, I also plan to send to the Bylaws Committee some recommendations for changes in the annual elections of officers, including a new office--speaker of the House of Delegates.

The office of president of the Medical Society of Delaware must be responsive to the needs of all members. Thus, my door, my telephone is always open. I expect to be a very visible presence throughout the state during the next year--I am not big on national meetings--there will be enough local problems to keep me busy.

Again, thank you for giving me the opportunity to serve as your president--I know our 200th anniversary will be very special. Thank you.

Henri F. Wendel, M.D.
President

THE EDITOR'S FAREWELL

The issue of *Delaware Medical Journal* in which this editorial appears is the last of volume 60. During those 60 years, the *Journal* has had only four editors: Dr. W. Edwin Bird, 1929-1956; Dr. Henry Clagett, 1956-1967; Dr. Robert B. Flinn, 1967-1979, and myself, 1980-1988.[1]

Shortly after Dr. Flinn became editor, I volunteered to help. Dr. Flinn very soon appointed me assistant and then associate editor and allowed me great latitude in developing the *Delaware Journal* throughout his tenure as editor. Thus, although my official editorship is shorter than Dr. Bird's phenomenal 27 years, I have worked closely with the *Delaware Medical Journal* for more than 20 years. The various aspects of the job, particularly soliciting, selecting, and editing papers, have always been highly pleasureable activities for me; when they became less so, I knew it was time to step down.

Some of the features introduced during my tenure include illustrated covers, focused issues with contents largely selected by their guest editors, In Black and White, Grand Rounds, Medical Classics, Viewbox, and an increased number of book reviews, almost all by local physicians.

Although medical literature is as old or older than the Ebers Papyrus, medical journals as such appeared in the 18th century. At first, their content was primarily case reports which had already been orally presented at some one or another society meeting. In this country, as might be expected, the oldest medical journals are Eastern; the best known, *The New England Journal of Medicine*, originally the organ of the Massachusetts Medical Society, recently celebrated its 175th birthday.

Several years ago, Dr. William Holloway found *DMJ* on the library shelves in China. As *DMJ* is included in the Index Medicus and the current computer indices, articles in our journal engender requests for reprints from all over the world. I've had requests from Czechoslovakia, from Hungary, from Mexico, from Spain, from India. On the other hand, the larger medical libraries in the U.S. now frequently do not display state journals even though they receive them.

I've been pleased and proud to edit *Delaware Medical Journal*. I've tried to make it interesting and relevant, and to keep it honest. Many individuals have given me a great deal of help, including Mrs. Mellita Phillips, Mrs. Anne Bader, Mrs. Beverly Dieffenbach, Mrs. Henrietta Moore, and, most recently, Mrs. Anne Spruance, as well as each year's editorial board and other physicians asked to advise on specific manuscripts, and numerous others.

There are fashions in medical journals as in everything else. State medical journals are becoming increasingly rare. There is so much for doctors to read and specialization is so prevalent that many of the remaining state medical journals no longer make any pretext of being scientific and are instead admittedly newsletters for their states, limiting their content to exhortatory advice and discussions of socioeconomic importance to their members.

With this issue, my influence on the *Journal's* contents comes to an end. Dr. E. Wayne Martz becomes the fifth editor of the new series.

Keep reading!

Bernadine Z. Paulshock, M.D.

Note:

1. There was also a *Delaware State Medical Journal* published for 13 years from 1910 to 1922. At that time the DSMJ merged with the *Pennsylvania Medical Journal*. The combined journals were published as the *Atlantic Medical Journal* which itself ceased publication after six years, their "joint aspirations...seemingly unattainable" as someone, probably Dr. Bird, explained in Volume 1 of the new series. None of the libraries in the vicinity has copies of the first volumes; I hope someday to be able to see them in the Library of Congress.

The Journal's name was changed from *Delaware State Medical Journal* to *Delaware Medical Journal* in 1960 because it was too often assumed to be a state hospital publication instead of a state medical society publication.

THE NEW EDITOR'S INTRODUCTION

This issue of the *Delaware Medical Journal* marks the transition from Dr. Bernadine Z. Paulshock to me as editor. Dr. Paulshock resigned as of "the end of the year," but since the fiscal year of the Medical Society of Delaware ends with the annual meeting, our new President, Dr. Henri F. Wendel, has invoked his prerogatives and decided upon that event as the change date. However, since most of the work of stimulating and generating and collecting the material for an issue takes place months ahead of time, there should be no question or doubt that this is still Dr. Paulshock's issue. She did the hard work. In fact you may still detect her fine hand in the January issue and later ones as well. In my mind it will still be her journal for a long time. She has put so much of herself into it that her imprint will remain.

This issue is unusual in other ways as well. It is written in very large part by health personnel who are not physicians. The writings are the work of the staff of Lyman Olsen, M.D., our very capable Director of the Division of Public Health. We have proofread for typos, spelling and syntax, but other than that it is the Health Department talking. I hope you will look it over carefully. By far the largest section is a description of the services available to you through your Health Department. A good and thoughtful physician will make use of those services in the treatment of patients. There are two brief pieces on new laws and new birth and death forms you will have to fill out and sign in the future. Then there are two reports of investigational or statistical analysis of problems. We wind up with an editorial by Dr. Olsen on Public Health as a career. I echo his sentiments in a brief editorial of my own.

In taking over as Editor, one of the conditions of my acceptance was that Herbert Keating, M.D., would agree to be my Associate Editor. I believe that most of you know Bert and have the highest regard for him as a person and as a physician. You may get to know him better as you read future issues of the *Delaware Medical Journal.* We have jointly composed a few paragraphs on how we view the *Delaware Medical Journal* - our goals and aspirations for it. We expect to take those goals out of our desk drawers from time to time to see how we are doing.

E. Wayne Martz, M.D.

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DELAWARE MEDICAL JOURNAL

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THE DIVISION OF PUBLIC HEALTH

Lyman J. Olsen, M.D., M.P.H.

The Division of Public Health is one of 11 Divisions which operate within Delaware's Department of Health and Social Services. In addition to public health activities, the Department offers a variety of social services, including job placement, food stamps, community homes for the mentally retarded, drug and alcohol counseling, and programs for the elderly. The Division of Public Health, in concert with other agencies within the Department, is striving to promote the health and welfare of all the people of Delaware.

To carry out its diverse responsibilities, the Division of Public Health employs about 1,600 people and has an operating budget of approximately $58 million. The Division is made up of two main sections: Community Health, and Facility-based Long Term Care.

Community Health services ranging from water supply monitoring to well child clinics are provided through three county health units and a network of 21 clinic sites.

The Long Term Care Section is composed of several facility-based services including Respite, Residential, and Day Care programs. These services are provided through the Division's three institutions: Delaware Hospital for the Chronically Ill, Emily P. Bissell Hospital, and the Governor Bacon Health Center.

This issue of *Delaware Medical Journal* addresses a number of select services provided by the Community Health Section, but it is by no means a comprehensive account of all the Division's activities. Further information regarding Delaware's public health services is provided in the Division's annual report, *Progress and Priorities in Public Health*. Copies are available by writing the Director's Office, Division of Public Health, PO Box 637, Dover, Delaware, 19903, or by calling 302-736-4700.

Dr. Olsen is Director of the Division of Public Health, State of Delaware.

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PUBLIC HEALTH SERVICES AVAILABLE IN DELAWARE

THE DELAWARE STATE TUMOR REGISTRY

The Delaware State Tumor Registry, which until 1987 was a component of the Delaware Cancer Reporting Service, is now directly administered by the Division of Public Health and is located on the grounds of the Emily P. Bissell Hospital.

The reporting of cancer cases to the State Registry by all hospitals and laboratories was made mandatory in 1980 by the passage of the Delaware Cancer Control Act; however, most hospitals have been reporting voluntarily since 1972. Presently, the Registry contains demographic, occupational, diagnostic, therapeutic, and follow-up information on over 48,000 Delawareans diagnosed as having cancer.

The Cancer Control Act defines both the nature and purpose of the State Registry: it is to serve as a "control data bank of accurate, precise and current information regarding the subject diseases" and further, this data bank is to be used for "the recognition, prevention, cure, or control of such diseases." The Registry staff works in close cooperation with Public Health agencies, hospitals, and private health care systems, and can draw upon the expertise and advice of the members of the newly chartered Advisory Council for Cancer Control.

The State Registry has recently completed and published its first statistical report in several years. The report, *Cancer in Delaware, 1980-1985*, includes incidence, stage distributions, and survival data. The report is intended to serve as an important tool to guide the development of a coordinated cancer control plan for Delaware. For example, the Registry has shown a significant reduction in the incidence of *in-situ* carcinoma of the cervix while documenting an increase in advanced cases in women in Sussex County. In addition to generating descriptive statistics outlining general trends in Delaware, the Registry is able, with the assistance of a consultant epidemiologist, to investigate what appears to be cancer clusters and conduct a systematic surveillance of cancer incidence in the state by census tract divisions.

Another important function of the Delaware State Tumor Registry is serving as an informational resource to the wider health community. The Registry data base more and more is used by hospital and cancer programs, cancer committees, private physicians and non-profit health agencies. For a copy of *Cancer in Delaware, 1980-1985*, or for further information on how this data base could be helpful, contact the director of the Delaware State Tumor Registry at 995-8605.

Allan Topham

Mr. Topham is Director of the Delaware State Tumor Registry.

"IN TOUCH" TELEPHONE MESSAGE SYSTEM FOR TEENAGERS

The Delaware Division of Public Health has developed a unique taped telephone message system on human sexuality and related topics targeted at teenage boys. Several taped message systems such as Tel-Med are in operation across the nation, but In Touch, developed in September 1986, as part of a male involvement initiative in Delaware, is the only system emphasizing the informational needs of teen boys. It is available statewide, free to all callers.

This approach offers several educational advantages for reaching teen boys. Fearful of embarrassment and loss of image, teens and especially boys often pretend to know more than they actually do about sexuality. In Touch provides opportunities for teens to educate themselves without feeling humiliated or threatened. There are messages available for female concerns as well. With over 50 three-to-five minute messages, teens can listen to what they choose, and with 24 hour access, whenever they choose. In some cases, such as nights or weekends, In Touch may be the only immediate source of information on such urgent topics as condom use, signs of pregnancy, sexually transmitted diseases, and AIDS. The automated system allows for complete privacy and anonymity. No operator is required. In Touch only needs a touch-tone phone, which can be found in approximately two thirds of Delaware homes, and a directory of topics.

The content of the messages was developed by teenagers, nurses, physicians, counselors, health educators, parents, and teachers. The entire approach is geared to young people's developmental level, comprehension, interest, and sense of immediacy. All messages were written with emphasis on sensitivity to gender role stereotyping, race, religion, and values. A variety of voices have been used to reflect community diversity.

In a state with a total population of less than 700,000, more than 21,000 calls were received in the first year of operation. Monthly call volume has averaged 1,125, with the highest monthly usage being 3,682 calls. Monthly call volume during the school year is at least twice that of summer months.

Of the most frequently called messages, 42% listened to male oriented topics, 35% listened to female oriented topics, and 23% listened to gender neutral topics. Messages dealing with male responsibility, pregnancy, dating, puberty, homosexuality, and sexual myths are the most popular.

The highest calling rate occurs during the after school period from 3:00-6:00 p.m. (9.1 calls per hour), followed by 6:00-11:00 p.m. (8.3 calls per hour), 8:00 a.m. to 3:00 p.m. (5.2 calls per hour) and 11:00 p.m. to 1:00 a.m. (0.3 calls per hour). It is likely that teenagers feel most comfortable listening to messages at home, in private while parents are still at work.

In Touch has been primarily marketed to schools and community youth groups. The program is explained to teens, and a brochure listing the messages is distributed during health education sessions conducted by the Division's health educators. Brochures and a series of eight posters encouraging male responsibility and listing the In Touch telephone numbers were also sent to every secondary school in Delaware for distribution and posting.

In Touch has been an effective and efficient method of delivering health education messages. It is a relatively permanent, round-the-clock service that can last for many years with only periodic message update. School authorities have welcomed In Touch as an adjunct to classroom health education. Free choice in message selection has made In Touch a politically neutral approach to sexuality that schools can promote.

Like any form of education, it has been difficult to determine if listeners act on the information and advice received. The call volume and selection of topics, however, are an indication of demand for accurate sex information.

Privacy, immediacy, accessibility, economy, and variety of choice have made In Touch a successful and creative addition to existing sex education media.

Lucille P. Siegal, M.P.H.
Todd Krieble, M.P.H.

Ms. Siegal is the Director of the Office of Adolescent Health Services in Dover. Mr. Krieble is a Health Educator.

PUBLIC HEALTH NUTRITION: HELPING INDIVIDUALS, SERVING COMMUNITIES

There is little question among physicians as to the role of the dietitian. Most have encountered the hospital dietitian and may have experienced the benefits of patient referral to the private practice dietitian. On the other hand, the Public Health nutritionist may be less well known to the physician and therefore less well utilized.

The Public Health nutritionist has two major roles in the community and can serve as a vital link for the physician. They are responsible for providing direct nutrition services to individuals and families. In addition, they influence nutrition knowledge and practice, and participate in policy setting on broader health issues, advocating healthy lifestyles for prevention of disease and promotion of wellness. In both roles, the skills of needs assessment, planning, and evaluation are applied.

Community Involvement

As a primary activity, the assessment of the nutritional needs and resources of the community is initiated. This is an ongoing process involving the participation and the coordination of outside groups and agencies.

Within the Public health system, the nutritionist participates in the development of a dynamic plan for the community, which includes the services of nutrition screening and referral, assessment, and follow-up within Public Health programs for people of all age groups.

The special supplemental feeding program for Women, Infants, and Children (WIC) is the most well known nutrition program. The value of WIC in improving nutrient intake of this target population is well known. Evaluation of the program has credited WIC with increasing the birth weight of infants born to mothers on the program,[1] and decreasing the incidence of anemia in children receiving these benefits.[2]

Public Health nutrition in Delaware is, however, more than the WIC program. Nutritionists work in conjunction with the American Heart Association and other agencies. Through public education the nutritionist provides sound information and combats the potential for dangerous health practices. The nutritionist is a resource to schools, institutions, and private groups.

Participation in statewide councils, such as the Delaware Center for Workplace Wellness, affords the opportunity to set standards for quality nutrition education and weight loss programs in the workplace. Involvement in task forces, such as the Infant Mortality Task Force, the Adolescent Pregnancy work group, and the task force for the Prevention of Mental Retardation brings the influence of good nutrition practices to the eyes of the public, resulting in changes in community health policy and practices.

Services to Individuals and Families

While nutrition is only one of many concerns the physician must address, it is the primary concern of nutritionists. Use of a nutritionist in patient care is beneficial to both the physician and patient, as the nutritionist has the time needed to teach and counsel.

When a referral from a physician is received by the nutritionist, contact is made by phone or letter to set up an appointment. The nutritionist is able to meet with the patient in a variety of settings, including the home, or locations suited to patient needs. A data base of medical history, social and family situation, economic, and environmental information is collected, in addition to the nutrition and dietary history of the patient. This specialist has the training to personalize diets to fit the patient's lifestyle and will select teaching materials suited to the educational level of the patient.

Helping the individual fit the recommended changes into his or her lifestyle is the challenge.

The nutritionist's knowledge of human behavior, and techniques for effecting change are used in shaping the client's behavior. Changes in eating habits often involve a number of visits over a period of months; during this time the nutritionist can act as the liaison between the client and the physician. The number of visits needed to help the client achieve independence may vary, but self-sufficiency is the ultimate goal in individual counseling. The nutritionist can establish a rapport with the family, particularly if home visits are indicated. By establishing that trust, the nutritionist's visit can be an avenue to other health care needs, or to greater compliance with the physician's recommendations.

Evaluation is an ongoing process. The nutritionist evaluates the nutritional care plan and counseling techniques, as well as the patient's behavioral changes and health outcomes (weight reduction, decrease in serum cholesterol), including this in the report to the physician.

Conclusion

Nutrition is important, not only to the individual following a specified diet, but also to the welfare of the population as a whole. Providing direct nutrition services, as well as influencing community nutrition policies and programs, are functions in which the Public Health nurtitionist excels. The Public Health nutritionist helps the physician in terms of individual client management, and serves as a resource in the community.

Anita M. Muir, M.S., R.D.
Elizabeth Fearnow, M.Ed, M.P.H., R.D.

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Ms. Muir is Program Director of Delaware Public Health Nutrition; Ms. Fearnow is Supervisor of Kent and Sussex County's WIC Programs.

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AIR FORCE

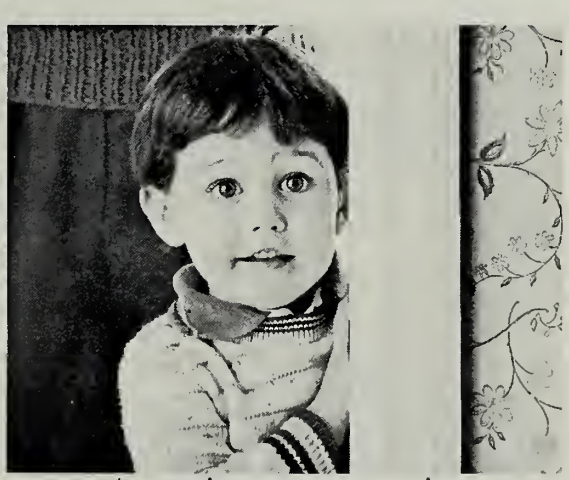
PSYCHOLOGICAL SERVICES AS AN INTEGRAL COMPONENT OF DELAWARE'S PUBLIC HEALTH PROGRAM

Public health has always emphasized that prevention of medical problems is preferable to treatment, and that intervention is better provided at earlier stages than later. The Delaware Division of Public Health includes an active Office of Psychological Services which also emphasizes prevention and early intervention. This office helps families by providing the kind of parenting skills information which fosters optimal child development in all areas by intervening at early stages of emotional and behavioral problems and by preventing potential ones. Primary attention is given to those high risk families with children under the age of five who are already served by other Public Health programs. These families generally do not have access to the parenting help which would be provided through private health care providers.

The emphasis on prevention and early intervention for emotional and behavioral problems may take many forms within the high risk population served by the Office of Psychological Services. An infant who is sick or premature may not be as responsive as a full term, normal one; parents of such babies may feel depressed, guilty, or unable to fulfill the demands of caring for their children. These parents may need understanding and support as well as specific suggestions for ensuring their baby's optimal development. Other parents may need help as their children become toddlers with issues such as discipline or toilet training. Such early intervention can prevent normal parenting concerns from becoming mental health problems.

To promote the development of healthy children within healthy families, the Office of Psychological Services provides a range of services which can start right after a baby's birth and continue until the child enters school. The service delivery model used consists of three components: consultation, direct services, and training. This model allows the psychologists to provide more services by working indirectly through other Public Health staff as well as directly with children and families. The result is that more families have access to psychological services, thus effectively using limited psychological time.

The primary component, consultation, is provided to Public Health staff members and to other agencies upon request. Consultative help may be provided on such topics as parenting, early signs of emotional disturbance, appropriate behaviors, and appropriate behavioral management strategies. Consultation with Public Health staff may also involve providing support help and information for families who are being followed by a staff member such as a public health nurse, speech pathologist, or nutritionist. Such consultation may be on a one-time or an ongoing basis.



Another component of Psychological Services is providing direct services to children and families. Time-limited evaluation and counseling to families are provided through referral to Psychological Services by a Public Health staff member. The goal of providing direct services at the early stages of behavioral and emotional problems is to prevent the development of more serious and more difficult to treat mental health problems. If more serious psychological problems are identified, the Office of Psychological Services refers these children and their families to more appropriate child mental health agencies.

The staff and parent training component of the services delivery model involves training for Public Health staff and outside agencies and personnel, as well as parent education. Staff training has involved workshops on topics such as hyperactivity, infant stimulation, and feeding problems. The parenting aspect has included talking with groups of parents as well as the preparation and distribution of written materials, such as the "Tips for Parents" series, which covers child rearing concerns such as toilet training, discipline, and temper tantrums (a free sample set of these tips may be obtained from the Office of Psychological Services, PO Box 637, Dover, Delaware, 19903).

In order to promote the healthiest possible children and families, a comprehensive public health system should provide a wide range of programs and services which address all aspects of development. Using the model developed by Delaware's Office of Psychological Services, those programs which address prevention of and early intervention for emotional and behavioral problems can be provided in a timely and cost-efficient manner.

Jill Linden, Ph.D.
Dorilyn English, Ph.D.

Drs. Linden and English are on staff at the Office of Psychological Services.

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DELAWARE'S BUREAU OF ENVIRONMENTAL HEALTH

All too often, physicians and the public alike recognize that there is a Delaware environmental control agency which monitors environmental hazards to lower animals, plants and ecosystems, but few practitioners know of the existence of the Public Health agency which handles environmental hazards which affect human health, the Bureau of Environmental Health (BEH). While the Department of Natural Resources and Environmental Control is responsible for the clean-up of contaminants and their environmental impact, it is the BEH that must evaluate and assess the risks to health. Both agencies work cooperatively to determine if a facility should be closed, an area evacuated, or a water supply banned.

For over 25 years, BEH has focused on preventing and reporting environmental hazards through health assessments (ie, inspections, surveys, or investigations). You may be aware of some of the environmental health assessments, but not aware of the fact that the services were an integral part of Delaware's Public Health activities. The Environmental Health staff assesses the safety of our drinking water, the sanitation of our public eating places, milk, excessive exposures to x-rays or toxic chemicals, and contamination levels on beaches, pools, campgrounds, or in day care facilities.

There are many more activities performed by the Environmental Health staff, such as assistance to workers in their occupational setting, including medical/dental offices, participation in the State Emergency Response Team (SERT), and monitoring of air quality in homes and schools (eg, radon and hazardous chemical monitoring). Technology now allows the assessment of risk in several areas so that proper management of those hazardous situations can be undertaken. This is a formal qualitative and quantitative analysis of data provided on medical, biological, chemical, and physical sources to arrive at a risk statement on exposure and the possible health consequences (eg, cancer risk from the chemicals in given hazardous waste sites).

If you think your patients would benefit by contacting the Bureau of Environmental Health on suspect environmental hazards, refer them to the BEH in-state number, 800-554-4636. After all, your epidemiological suspicions and prompt action may do more to prevent serious environmental threats to individuals or communities than all the "after the fact" emergency responses.

Lawrence J. Krone, Ph.D., M.P.H.

Dr. Krone is the Director of the Bureau of Environmental Health in Delaware.

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REGULATING HEALTH CARE

State health regulations are promulgated by the Delaware State Board of Health. The regulatory enforcement of health standards is conducted by the Office of Health Facilities Licensure and Certification within the Division of Public Health.

This regulatory office is responsible for monitoring 13 licensure programs and 15 federally certified (Medicare and/or Medicaid) programs of health care providers. Their responsibility ranges from the acute care setting in a hospital to a small family care home of two or three beds. There are approximately 450 health care providers throughout the state of Delaware that are subject to routine inspections.

The Delaware State Board of Health has adopted new categories of health regulations in accordance with the Delaware Code amended by the State Legislature for Free Standing Surgical Centers, Free Standing Emergency Centers, and Free Standing Birthing Centers. These new provider categories are defined as:

1. *Free Standing Surgical Center* is a facility which operates exclusively for the purpose of providing surgical services to patients who do not require hospitalization. It does *not* include: a. a facility that is licensed as part of a hospital; b. a facility that provides services and/or accommodations for patients who stay overnight; c. a facility which is used as an office or clinic for the private practice of a physician, podiatrist, or dentist.

2. *Free Standing Emergency Center* means a facility, physically separate from a hospital, which uses in its title or in its advertising, the words "emergency," "urgent care," or parts of those words or other language or symbols which imply or indicate to the public that immediate medical treatment is available to individuals suffering from a life threatening medical condition. A facility rendering such care is capable of treating all medical emergencies that have life threatening potential.

3. *Free Standing Birthing Center* means any public or private health facility or institution which is not licensed as a hospital or as a part of a hospital and provides care during delivery and immediately after delivery for generally less than 24 hours.

There are numerous federal legislative changes required by the Omnibus Reconciliation Act of 1987 concerning nursing home reform, home health agencies, mental retardation facilities, etc, that are to be enacted in each state by 1989-1990. For further information concerning state or federal regulations, contact the Office of Health Facilities Licensure and Certification, 3000 Newport Gap Pike, Wilmington, Delaware, 19808.

James Harvey, M.P.H.

Mr. Harvey is Director of the Office of Health Facilities Licensing and Certification.

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THE PUBLIC HEALTH NURSE: CAREGIVER, TEACHER, DETECTIVE, FRIEND

When the doctor called, there was frustration in his tone. "All I asked this patient to do was soak her left foot twice a day. The wound is getting worse and she's obviously not following through." The pediatrician sounded concerned. "This baby is not gaining weight. Would you see what's going on at home?" The infection control nurse at the hospital picked up two Hepatitis A cases from the same town in one week. Could there be a common source? The wheels have been set in motion for public health nursing care. But many physicians, allied health professionals, and even other nurses are unaware of the wide variety of services available to patients at home or in the public health clinics.

Public health nurses are committed to a holistic, family centered approach to preventive health care. Using available community resources, the expertise of other disciplines such as nutritionists and social workers, and a network of health care professionals, the public health nurse guides families through the health care maze and assists them in solving problems as basic as food, clothing, housing, or transportation, or as complex as high tech medical equipment in the home.

Within the clinics, a cadre of trained OB/GYN, family planning, and pediatric nurse practitioners provide physical assessments, screening tests, and referral for identified abnormalities for patients from birth through their senior years. Prenatal care, birth control methods, immunizations, and health teaching on such topics as parenting skills, healthy lifestyles, and coping with chronic disease are offered on a free or sliding scale fee basis. Clinic hours vary from site to site with early morning or evening hours available at many locations.

Public health nurses are responsible for prevention and follow-up of communicable diseases in our communities. They search for source cases and contacts for such disease conditions as tuberculosis, sexually transmitted diseases, childhood diseases, even head lice. Using epidemiological skills, they identify infected patients, assist them in obtaining testing and treatment, and teach them how to prevent reinfection or further spread. Treatment is available through the clinics for many communicable diseases, and compliance with that treatment is a primary concern.

Within the home setting, public health nurses have the ability to assess the physical environment, family and neighborhood psychosocial relationships, health behaviors, and the health status of each member of the household. From this comprehensive data base, an individual plan of care is developed with the family which may include elimination of safety hazards, improvement of parenting skills, development of support systems, and care for identified health problems or poor health behaviors. Home health care services are available in Kent, Sussex, and southern New Castle Counties, and all major insurances are accepted.

The job of the public health nurse is at times frustrating and overwhelming. After finally getting an ophthalmology appointment for the infant born two months prematurely only to find the mother overslept for lack of an alarm clock, or when the 18 year old mother of three says she's pregnant again, public health nurses may wonder why they chose this field of nursing. But successes can be measured in small increments: the pregnant girl who comes in for care in her first trimester, the child who completes his immunizations on time, or the emphysema patient who finally quits smoking are significant victories for the staff.

And what of the referrals mentioned earlier? The first patient couldn't soak her foot--she had no water in her home and had to carry it from a neighbor's, a fact she was too embarrassed to tell her doctor. A teenager in the neighborhood was enlisted to bring her water until repairs could be made, and he volunteered to do her yard work as well. The baby soon began to gain weight once the mother began receiving formula regularly through the WIC program. She had been diluting the formula with water to make it last. The Hepatitis A cases were unrelated, but contacts were identified and arrangements made for administration of immune globulin.

Public health nursing is a unique field requiring independent judgment, interdisciplinary approaches, and creativity on the part of the staff, and continuous updating and adding to their knowledge, not just in medicine or nursing, but also on available community and state resources.

Barbara DeBastiani, RN.C., B.S.
Susan Shank, RN.C., B.S.
Ms. DeBastiani is a Public Health Nursing Supervisor. Ms. Shank is a Pediatric Nurse Practitioner.

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COMPUTERIZED HEALTH RISK APPRAISAL: A USEFUL TOOL FOR THE CLINICAL SETTING, TOO

Health Risk Appraisal (HRA) is an educational and motivational tool most frequently used in the context of comprehensive workplace or community health promotion programs. However, a booklet describing the newest HRA tool from the Carter Center of Emory University in Atlanta notes that it is now being used "increasingly by doctors in private practice."

An HRA provides a personalized estimate of an individual's risks of death or major illness during the next ten years. A computer program analyzes the individual participant's answers to a questionnaire about health habits and history, and uses national data on risk factors and mortality to calculate current risk. That risk estimate is usually expressed in terms of either "risk age" or a health score.

A second part of the HRA makes recommendations for changes in personal habits, and for routine tests and examinations, which can help the individual to improve health status and lower the risk age. Patients should be aware that an HRA is a statement of probability and not a diagnosis of disease. It is not a substitute for examination or health history, but it can be an additional tool to make the physician and patient aware of lifestyle habits which may be affecting the patient's health.

Of course, most patients who smoke or are overweight already know that they should quit smoking or lose weight. Yet many people do not act on that knowledge. Health Risk Appraisal is helpful because it uses a scientific data base to give individuals precise information. Often, they are not aware of how several factors may combine to dramatically increase their risk of dying. Or they may not be aware of how many of the leading causes of death for a person their age have smoking or obesity as a leading risk factor. The personalized, scientific information provided in an HRA can provide the motivation to take action which vague, general knowledge often does not provide.

For many years, the Center for Health Promotion and Education of the Centers for Disease Control has developed and disseminated a popular, computerized version of HRA. The Division of Public Health, through its Office of Health Promotion and Education, was the focal point for training and distribution of that HRA tool in Delaware.

Although CDC is no longer directly involved in HRA development, the work has been taken over by the Carter Center of Emory University, part of the Carter Presidential Center in Atlanta. Using the HRA Update Project, and working in close cooperation with CDC and other scientific groups, the Carter Center developed a new HRA with many updated features. The Division of Public Health is now serving as a focal point for the Carter Center "Healthier People" HRA in our state. We are responsible for promoting its use, for accepting applications into the HRA Users' Network, for training all new users, and for providing consultation and follow-up services to users.

Fortunately, the Carter Center has obtained adequate funding to continue development in the HRA field, and to provide periodic updates of the existing software. As more users join the nationwide HRA Network, the Carter Center hopes the project will become self supporting.

Information packets about the Carter Center "Healthier People" HRA, including samples, requirements, cost, and training, are available to any health professional. If you are interested in joining the Users' Network, contact the Office of Health Promotion and Education, Division of Public Health, PO Box 637, Dover, Delaware, 19903.

Fred N. Breukelman

Mr. Breukelman is Director of Health Education in the Office of Health Promotion and Education of the Division of Public Health in Dover.

GENETICS SERVICES IN DELAWARE

In 1984, the state of Delaware received a federal genetics services grant which resulted in the Division of Public Health's establishing a network for the provision of statewide genetics services. Prior to that grant, such services were available on a limited basis through the Alfred I. duPont Institute and the Medical Center of Delaware in the northern portion of the state. In 1988, the federal grant expired, and the state has assumed fiscal support of the Office of Genetics Services.

The Office supervises and coordinates services to the entire state, including clinical genetics and genetic counseling, neonatal metabolic disease screening, prenatal and preconceptual counseling, and educational services in genetics.

Clinical Genetics

Epidemiologic studies indicate that the prevalence rate of genetic disorders and birth defects identified at birth is about 1-2%, while the March of Dimes Birth Defects Foundation estimates that 1 in 20 children has a birth defect or genetic disorder, and 1 in 5 adults has a genetic disorder in his or her family. Of admissions to pediatric hospitals, 30-50% are for genetic conditions or congenital malformations.

Clinical geneticists assist primary care providers in identifying congenital malformations, clarifying multiple malformation syndromes, and diagnosing genetic disorders including chromosomal abnormalities (eg, Down's syndrome, Turner's syndrome, Fragile X syndrome, Trisomy 18), single gene defects (eg, cystic fibrosis, Tay-Sachs disease, hemoglobinopathies, Huntington disease, insulin dependent diabetes), and multifactorial traits (eg, neural tube defects, congenital heart malformations, hypertension).

Clinical genetics in conjunction with a cytogeneticist and assisted by genetic counselors provide genetic counseling to families who have a member with a condition which is or could be genetic. This team of genetic specialists also offers clinical teratology services to obstetricians, perinatologists and their patients, and helps families to understand and get access to available prenatal diagnostic tests.

The Office of Genetics Services provides partial support to clinical geneticists and a cytogeneticist in Delaware, and total support to two genetic counselors, one for New Castle County, and one for Kent and Sussex counties. Some 2500 families have been served by these various professionals over the past three and one half years.

Screening

Neonatal screening for genetic metabolic disease began in the United States in 1962 with the Guthrie Test for phenylketonuria (PKU). Since then, it has expanded so that in Delaware, newborns are now screened for PKU, congenital hypothyroidism, galactosemia, maple syrup urine disease, homocystinuria, and sickle cell anemia. Cost-benefit analysis studies have been performed in various states and countries, and all support the value of identifying these disorders, which are for the most part treatable when detected early. In Delaware, 99% of newborns have

been screened over the last five years. Ten babies, each with one of these heredity metabolic disorders, have been identified (1 in 4500), and treatment and counseling begun. Another eight to ten babies have been detected per year with sickle cell anemia. The families of these children have also been referred for treatment and counseling.

The Office of Genetics Services coordinates this screening program, with the laboratory work being done in the Maryland State Newborn Screening Laboratory. The Office provides quality control and assures that appropriate follow-up services are promptly available and accessible for babies who test positive.

Regular review of a Newborn Screening Program is essential. New tests are proposed from time to time and need to be judged with close attention to sensitivity (ability to detect individuals with the disorder); specificity (frequency of identifying unaffected individuals as affected); cost; ease of performance; degree to which the disorder being screened for can be treated or families counseled; and availability of services to promptly and comprehensively treat and counsel.

Prenatal Services

Amniocentesis, high technology ultrasound, maternal serum alpha fetoprotein screening, and chorionic villus sampling are all available in Delaware. The Office of Genetics Services supports and makes every effort to assure that these prenatal tests are available to families who wish them.

There is anecdotal evidence that some Delaware families are unable to have prenatal testing because of the cost. The Office is cooperating with local and regional groups such as The Middle Atlantic Regional Human Genetics Network, in studying the fiscal realities of providing genetics services. Third party payers reimburse for only a limited number of genetics services.

Families at risk for chromosomal abnormalities (including pregnant women of advanced reproductive age), for neural tube defects, and for selected single gene disorders have been candidates for amniocentesis and chorionic villus sampling for a number of years. In the last three to four years, tremendous progress has been made in using the new recombinant DNA technology in prenatal diagnosis and in carrier detection. Within the last two years, it has become possible to diagnose cystic fibrosis and PKU in more than 95% of families at risk and to diagnose hemoglobinopathies in the fetus without the high risk procedure of fetal blood sampling. Virtually every month, another genetic disorder becomes diagnosable by DNA studies. Huntington disease, neurofibromatosis, and probably insulin dependent diabetes mellitus are on the verge of being reliably diagnosable.

The American College of Obstetrics and Gynecology and the American Society of Human Genetics have urged that maternal serum alpha fetoprotein (MSAFP) screening be offered to all pregnant women. The test is well standardized and is useful in identifying women at an increased risk of bearing a child with a neural tube defect, Down's syndrome, and other rarer malformations. As with any screening test, MSAFP screening should only be offered if prompt, reliable, accessible, and up-to-date follow-up services are available to the woman who has either a high or low serum alpha fetoprotein. In this case the services required are counseling, high technology ultrasound, and amniocentesis.

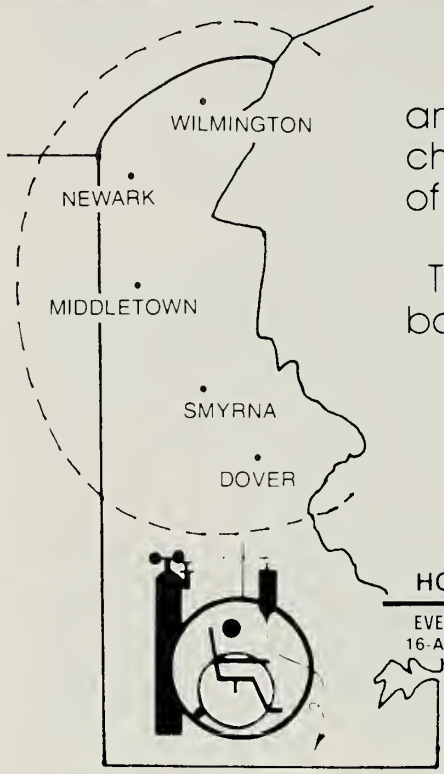
Education

Literature appropriate for consumers and providers alike is being produced by the Delaware Division of Public Health Office of Genetics Services. Topics discussed include preconceptual counseling, prenatal counseling, newborn screening, sickle cell anemia and sickle cell trait, risks to pregnancy, and MSAFP screening. Educational lectures and symposia in genetics are regularly produced for physicians, nurses, teachers, social workers, other service providing professionals, and consumers.

Modern, sophisticated genetics services are required if the citizens of Delaware are to enjoy comprehensive health care. Financing, quality control of tests and procedures, accessibility of services, follow-up of case finding, and education of professionals and consumers are major continuing issues to be dealt with by the Office of Genetics Services and the health care providers of this state.

Louis E. Bartoshesky, M.D., M.P.H.

Dr. Bartoshesky is on staff at the Department of Clinical Genetics at the Medical Center of Delaware, and is a pediatrician on staff at the HMO of Delaware.



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NEW LAWS AND THEIR IMPORTANCE TO DISEASE PREVENTION

Paul R. Silverman, Dr.P.H.
David E. Wolfe, P.A., R.N., M.P.H.

Introduction

Community-wide surveillance, treatment for the purpose of rendering a person noninfectious, screening for subclinical disease, elimination of potential environmental sources of disease, immunization, and education are among the important tools available to Delaware state health agencies to control infectious disease. Legislation, although not usually considered in this context, is another important tool. Recognizing that these tools must be used together and that any single approach alone will usually be inadequate, we report on legislation recently enacted which impacts on the control of three important health priorities in Delaware--sexually transmitted diseases (STD), AIDS, and rabies.

Sexually Transmitted Diseases

Aside from AIDS which will be discussed later, gonorrhea and syphilis are among the most significant STDs in Delaware, and provide a rough indicator of the incidence of other STDs. The rate of gonorrhea per 100,000 population has decreased in recent years, after peaking in 1985 at 722. However, the 1987 rate (528 per 100,000, representing 3,404 cases) was 63% higher than the national average. Of equal significance, 54 penicillinase-producing *Neisseria gonorrhea* (PPNG) cases were reported in the first six months of 1988, compared to 45 cases in all of 1987. PPNG now represents 3.9% of all gonorrhea in Delaware.

Dr. Silverman is the Delaware State Epidemiologist.
Mr. Wolfe is the Rabies Control Coordinator.

In contrast, syphilis morbidity in Delaware occurs below the national average, but with recent alarming increases. Early infectious syphilis (primary, secondary, and early latent less than one year duration) increased from 96 cases in 1986 to 116 in 1987; 94 cases were reported in the first half of 1988. In addition, from 1986 to 1987 increases in early infectious syphilis among women were pronounced (69%), while cases among men, particularly white homosexuals, decreased.

House Bill 599 was signed into law July 11, 1988, replacing 16 *Del. C.* Chapter 7, unrevised for more than 30 years. Key features of the new law are as follows.

- The State Board of Health is empowered to designate which diseases will be administratively considered sexually transmitted. Previously, only gonorrhea, syphilis, and chancroid were considered "venereal diseases." The advent of new diseases (eg, AIDS) or changes in policy can now be more easily accommodated.
- Changes to STD reporting requirements are significant. Laboratories which find evidence of a notifiable STD, or physicians and other health professionals who diagnose, suspect, or treat a notifiable STD must file (eg, mail or phone) a report containing certain information within 24 hours of the findings or suspected diagnosis. Specific reporting requirements and procedures will be communicated to the medical community at a later date. Disease investigators of the Division of

Public Health may contact the STD suspect without informing the suspect's physician, but only if necessary to protect the public health and after reasonable efforts to inform the physician fail.

- As in all states, Delaware has always had certain powers to cause the examination, investigation, and treatment of STD suspects, as well as apprehension and quarantine authority. The new law specifies clearly the procedures which will be used in such circumstances and the limitations on these powers, and ensures that the civil rights of the subject of any order are protected.
- In addition to syphilis, the new law requires that tests for gonorrhea and chlamydia be made on pregnant women. In addition, the tests will be performed during the third trimester as well as when first examined. It also grants authority to the State Board of Health to add other tests which will be performed during gestation.
- The new law specifies that information about STD clients, including HIV, shall be confidential and cannot be released except under certain conditions such as with the person's consent, or in a medical emergency.

About half of all reported syphilis and gonorrhea patients in Delaware are treated and investigated in state operated public clinics. The new STD law not only better positions the Division of Public Health to implement traditional disease control methods, but accommodates the possibility of new diseases and findings which lie ahead.

AIDS

Since the first official report in 1983, 118 cases of AIDS, as defined by the Centers for Disease Control (CDC), have been reported in Delaware, with 36 in the first half of 1988 alone. Of these, 58 are dead. Fourteen cases are women (12%), and 57 are black or hispanic (59%). Although the majority of patients are gay or bisexual men, the proportion of patients using IV drugs has more than doubled in the past few years, standing now at 23%. At least six patients were infected heterosexually. Patients have been reported throughout the state, including in the correctional system, but rates are highest in New Castle and Sussex Counties.

These statistics do not include patients living or being treated in Delaware who had onset of illness while residing elsewhere. Nor do they include persons who have symptoms of HIV infection not complying with the arbitrary CDC definition, or who may be asymptomatically infected. Clearly, the extent of the HIV epidemic in Delaware is greater than data on CDC-defined AIDS cases alone suggest.

The prevalence of HIV infection is difficult to estimate and is the subject of many national investigations. In Delaware, data from the Division of Public Health's anonymous counseling and testing clinics and some limited volunteer surveys in STD clinics and drug treatment centers give some estimates, but must not be generalized. This data tells us that as many as 15% of gay or bisexual men coming to our clinics are HIV positive, as are 6-8% of IV drug users. About 3% of heterosexual contacts of persons practicing high risk behavior are HIV positive. In contrast, 0.01% of blood donors and 0.16% of Delaware residents applying for military service are found to be HIV positive.

AIDS has medical, social and political implications. The purpose here is not to discuss the merits of various points of view in these arenas, but to outline House Bill 599 with relation to AIDS. Indeed, this law, originally proposed by the Division of Public Health's AIDS Advisory Task Force, was hotly debated. The underlying assumption of the law, which did not seem to be controversial, was that generally people have the right to be told when an HIV test was to be performed and that the test results will remain confidential. Specific features of the law are as follows:

- Health providers must obtain a patient's informed consent (written or oral) before performing an HIV-related test. Informed consent consists of: 1) an explanation of the test; 2) the procedure to be followed (including that it is voluntary); 3) how the results will be held confidentially; 4) how the test results relate to the natural history of AIDS; and 5) information about behaviors known to transmit HIV.
- Informed consent is not necessary when 1) testing is needed to provide emergency care; 2) in blinded research protocols; 3) in connection with anatomical gifts; 4) when a health care worker has been exposed to a patient's blood in a manner known to transmit HIV; and 5) when ordered by a court, provided that

the court adheres to specified conditions and the reasons for the order are compelling in a civil or criminal litigation.

- In many of the exceptions noted above, the patient still must be told that a test was taken and that the results could be made available to the patient. In addition, the results must be given to a patient with appropriate counseling.
- No person may disclose the identity of a person on whom an HIV test is performed or the results of the test. Here again, there are exceptions as disclosure is permitted 1) to the patient; 2) to a person authorized by the patient; 3) to health facilities and providers needing to know such information to provide health care to the patient;, 4) to providers of emergency care; 5) when in connection with anatomical gifts; 6) to health facility committees conducting program evaluation; and 7) to a court, provided that the court complies with specified conditions and the reasons to know the test results are compelling.
- Civil penalties ranging from $1,000 to actual damages plus reasonable attorney fees are allowed if provisions of the law are violated.

This law has considerations which go beyond the practice of disease prevention. However, since prevention of this disease relies at the present time solely upon education of persons at risk, we hope that perceived barriers to attainment of that education in counseling and testing clinics, physicians' offices, and other settings are removed. Perhaps too, this law makes future legislation more appropriate, given the codified right to consent and confidentiality.

Rabies

On November 5, 1987, the Newark Police killed a neurologically impaired raccoon which later was confirmed to be rabid by the Public Health Laboratory. This case represented extension of the mid-Atlantic raccoon epizootic into Delaware and the end of four decades of being a state free of terrestrial rabies.

The raccoon rabies epizootic began in Florida during the late 1950s and spread north and west. In 1977, a focus of raccoon rabies was detected in West Virginia, not contiguous with the southern epizootic. The focus, probably introduced by interstate transportation of raccoons by hunters or dog trainers, would eventually encompass both Virginias, Washington, D.C., Maryland, Pennsylvania, and now Delaware.

Delaware has identified 45 rabid animals since November 1987, divided among five species. Rabies in bats, however, circulate independently of terrestrial mammals and has been endemic in Delaware for many years. These animals, submitted for testing mostly by home owners when a human or domestic pet has been bitten, come from the northern and western parts of New Castle County. However, we regard all of New Castle County above the canal as endemic.

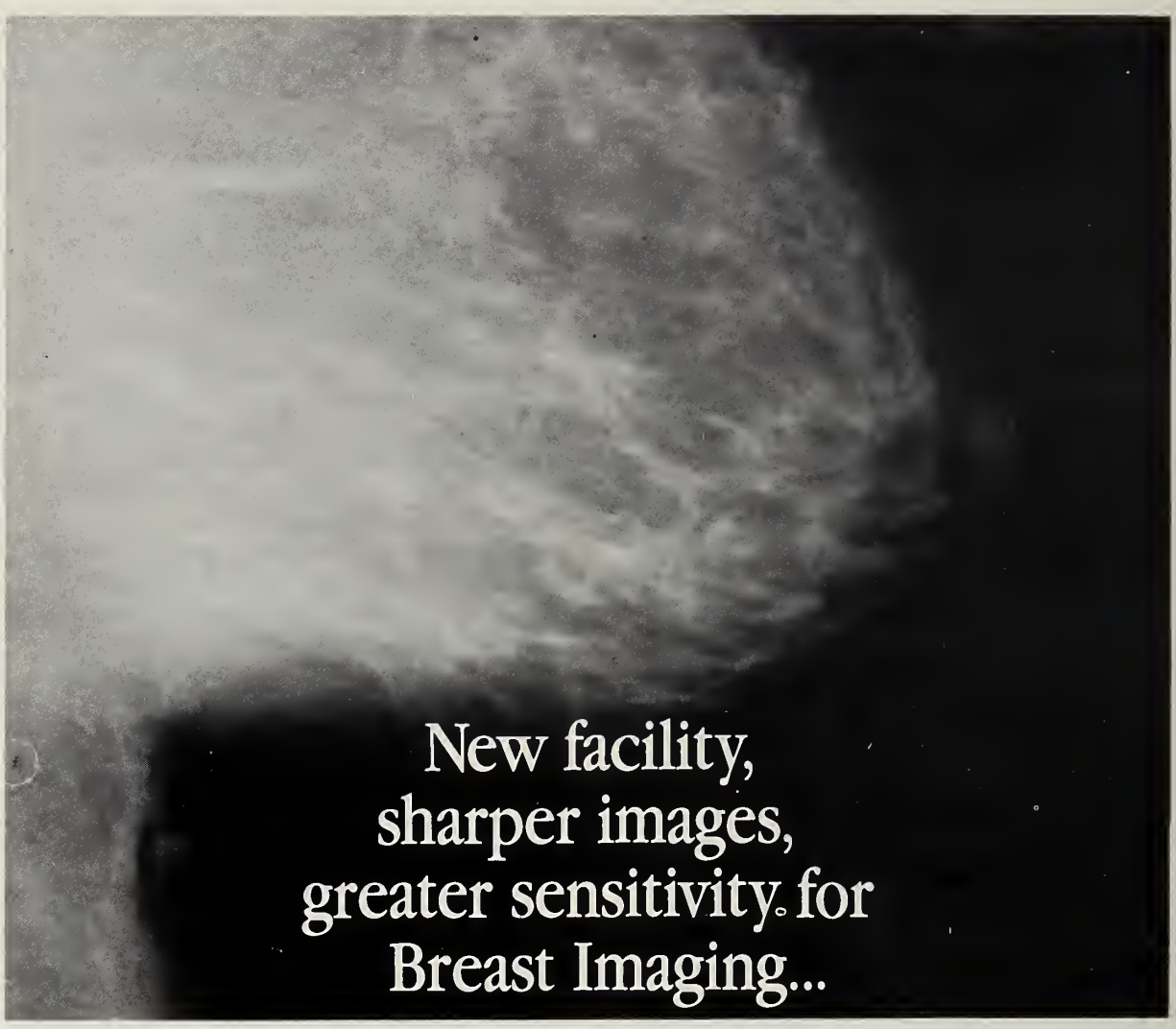
To prevent the spread of rabies to Delaware's domestic animal and human populations, the Department of Health and Social Services initiated a rabies control program consisting of surveillance, education, consultation, and coordination of appropriate responses to animal bites.

Contrary to the public's perceptions, before House Bill 360 was signed into law on May 13, 1988, there was no legal recourse to ensure that the potential threat to the health of an animal bite victim could be evaluated, except in select municipalities. Features of this law include:

- Both cats and dogs six months of age or older are required to be vaccinated against rabies. (In the mid-Atlantic region, the ratio of cat rabies to dog rabies was 16:1 in 1987.)
- Vaccinated dogs and cats which may have been exposed to rabies (eg, bitten by a raccoon) must be quarantined for 90 days. If unvaccinated, they must be euthanized or humanely killed or isolated for 180 days.
- Dogs and cats which bite a human must be quarantined for ten days. If the animal escapes, sickens, or dies within this period, the facts must be reported.
- Penalties are provided for obstructing the control and suppression of rabies as described in the law.

In response to this legislation, the Division of Public Health is developing an animal bite reporting system, and coordinating or funding agencies that can investigate bites and determine the circumstances relative to human health.

Information about rabies, quarantine requirements, animal bite investigations, and pre- and post-exposure vaccination, can be obtained by calling the Bureau of Disease Prevention (736-4745). During non-working hours a duty officer can be consulted by calling 736-9037.



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W-026, 6/88

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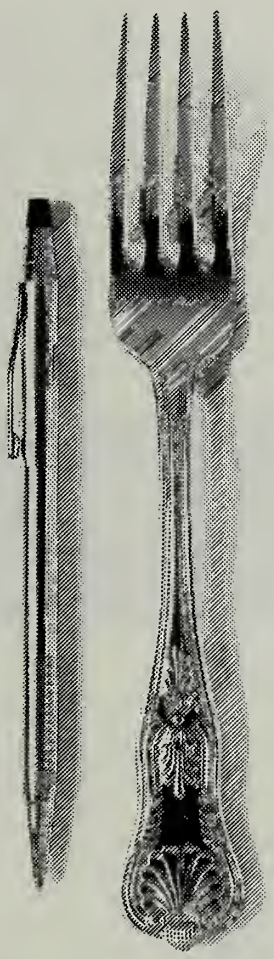

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NEW BIRTH AND DEATH CERTIFICATES

The Office of Vital Statistics, Division of Public Health is charged with the responsibility of collecting, maintaining, and issuing copies of vital events occurring in the state of Delaware. Beginning January 1, 1989, the Office will be instituting new certificates modeled after the latest U.S. Standard Birth, Death, and Fetal Death Certificates.

Delaware, along with the rest of the country, has adopted the new Standard certificates with some revisions to fit the needs of this state. Not only will these documents look different, they will capture additional data that is needed for health planning and evaluation purposes.

During late 1988, the Office of Vital Statistics will provide training to all those individuals or groups who have responsibility for completing birth, death, and fetal death certificates. Further information on death certificates will be forwarded to all Delaware physicians. Information on the new birth certificates will be available through hospital obstetrical units. Questions or comments may be addressed to the Vital Statistics Registrar at 736-4721.

Michael L. Richards

Mr. Richards is Director of The Vital Statistics Office.

CORRECTION

Because of a transcription error, a word was omitted in the article entitled "A Catholic Perspective on Religion and Organ Transplantation" by Thomas R. Ulshafer, S.S., Ph.D., in the September 1988 issue of the *Delaware Medical Journal.* The second sentence in the fourth paragraph on page 506 should have read: "First, how does one understand this second principle, that of love, so that it does not give a person an unlimited right to dispose of his/her own life and health for the good of another, i.e., to commit altruistic suicide?"

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DELAWARE STATEWIDE ADOLESCENT HEALTH STUDY - 1987

Lucille P. Siegel, M.P.H.

During April and May 1987, all Delaware public school districts administered the "Teen Wellness Check," an adolescent health survey to students in grades 8-12 (Fig. 1). To assure a representative sample of the population was obtained, the following steps were taken:

1. The districts' proportionate sizes by county were determined;
2. the schools; proportionate sizes by districts were assessed;
3. The proportions of the student population by county were calculated; and
4. The proportion of students by grade was assessed.

Labels with the name, grade, school, and district for all students in grades 8-12 were purchased from the Brandywine Data Center, Brandywine School District. The selection of individuals was conducted by consulting a random number table. The student's label was placed on the instruction page of the survey and torn off by the student prior to the return of the survey to assure anonymity.

The various approaches for disseminating surveys included distributing the questionnaires during homeroom class; sending the students to a classroom; and the school nurse contacting the students individually.

Each county's data was weighted according to the county's population; therefore, New Castle County received a weight of 60%, Kent County 21%, and Sussex County 18%.

We oversampled to assure receiving an adequate sample. The goal was to receive questionnaires from 414 students per county, with a total of 1,242. An initial 480 questionnaires were disseminated per county. There were 416 questionnaires received from New Castle County, 417 from Sussex County, and 432 from Kent County, with a total of 1,264. Thus, questionnaires were returned by 87% of New Castle County students, 90% of Kent County, and 87% of Sussex County teenagers.

The survey is comprised of 46 questions, with boys answering 40 questions and girls answering them all. The questions address health habits, attitudes, risk behaviors, knowledge, and family and individual health history. This automated questionnaire tabulates responses according to variables such as age, ethnicity, geographic locale, gender, etc. Cross tabulations of questions are available and provide more detail and refinement in identifying teens at risk, and the kinds of behaviors, attitudes, and knowledge they possess. The software provides individual printouts on the individual's risk behaviors, what to do to decrease the risks, and how the person compares to their peer group. Lastly, the software provides risk categories for the entire sample.

Of the 1,264 teens surveyed, 52% were girls and 48% boys. By grade the returned surveys were comprised of 8th graders 20%, 9th graders 22%,

Ms. Siegel is the Director of the Office of Adolescent Health Services in Dover.

10th graders 22%, 11th graders 17%, and 12th graders 18%. By ethnicity, the sample was 73% white, 22% black, 1% hispanic, 1% Asian, and 2% other. These samples are representative of the population at large.

Of the recorded scores, 34% of the teens scored "excellent" (lowest risk), 49% "fair," 12% "risky," and 5% "hazardous." Of the New Castle County teens, 36% ranked "excellent," compared to 38% of Kent County and 29% of Sussex County teens. "Fair" scores were recorded for 45% of New Castle County, 48% of Kent County, and 53% of Sussex County. "Risky" scores were recorded for 14% of New Castle County, 10% of Kent County, and 13% of Sussex, while 5% in both New Castle and Sussex Counties, and 3% of Kent County teens were ranked "hazardous."

Nutrition

Overall, dietary behavior among Delaware's adolescents is a serious concern. From the available data it is difficult to ascertain if teens are aware of what are considered to be proper nutrition habits or if they consciously choose unhealthy habits. For example, statewide, 59% of teens do not daily eat a variety of foods from the four food groups. There is little dissimilarity between boys and girls with regard to eating a balanced diet: 60% of boys and 58% of girls do not eat from the four food groups daily. Regardless of gender, the older teens are less likely to report eating a balanced diet.

In Delaware, 53% of teens report not eating breakfast at least five days a week. As expected, more girls than boys do without breakfast regularly: 50% and 45% respectively. For both sexes, the percentage not eating breakfast increases as teens become older. For example, only 35% of 8th grade boys compared to 53% of 12th grade boys and 48% of 8th grade girls compared to 63% of 12th grade girls report not eating breakfast at least five days a week. By ethnicity, 27% of white, 28% of black, and 38% of hispanic teens never eat breakfast.

Among teens, 3% are 20% or more over their ideal weight. There is no clear pattern among boys; however, among girls the majority of obesity is found among 11th and 12th graders.

Health Promotion/Wellness

Developing positive habits at young ages is important for several reasons. Numerous problems and chronic conditions can be prevented by adopting healthy behaviors and lifestyles. A higher percentage of boys report not brushing their teeth daily (7%), compared to girls (5%). For both sexes, one finds that fewer of the older students do not brush their teeth daily compared to younger students: 9% of 8th grade boys compared to 5% of 12th grade boys, and 10% of 8th grade girls compared to 2% of 12th grade girls. Not surprisingly, the majority of teens do not floss their teeth daily.

Along with personal health habits is knowledge of one's personal health status. This includes knowledge of one's allergies, medications, blood pressure, immunizations, weight, height, vision, etc. The results of this survey found 40% of both sexes are unaware of their immunization status. Generally, the older the student, the larger the percentage were aware of their immunization status.

Due to the increase in the incidence of breast cancer, it is very important to encourage young women to practice breast self-examinations on a monthly basis. In Delaware, 75% of girls report not conducting monthly exams. It is a positive sign, however, that as they become older, a larger proportion of the girls report conducting monthly exams.

Physical Fitness

Exercise/physical fitness is related to dietary habits and weight, but exercise is also important behavior. This study found that 48% of the teens report they do not get 20 minutes of aerobic exercise at least three days a week. It is not surprising that a larger percentage of boys exercise regularly compared to girls: 55% and 39% respectively. As teenagers become older regardless of gender, fewer exercise regularly.

By ethnicity, 29% of white, 25% of black, and 19% of hispanic teens exercise daily; 18% of white, 25% of black, and 13% of hispanic teens seldom exercise; and 8% of white, 14% of black, and 19% of hispanic teens never exercise.

The ability to swim is a survival skill. Overall, 9% of Delaware teens report now knowing how to swim. A significantly larger percentage of girls than boys do not swim: 11% and 6% respectively.

Smoking

Cigarettes are as much a drug as are alcohol, amphetamines, and barbiturates. All of the afore-

mentioned can be habit forming, and when used inappropriately are harmful to one's health and one's family and friends. The percentage of Delaware teens who report smoking is high: 18%. A higher percentage of girls report smoking than boys: 20% and 16% respectively. As students reach higher grades, larger percentages report smoking. Peer pressure appears to play a role in adopting the habit. Four percent smoke at least one pack daily. Boys are heavier smokers than girls: 5% and 3% respectively, while older teens are heavier smokers than younger ones. There is a twofold increase in smoking from 8th grade to 12th grade among boys and a fourfold increase among girls in the same grades. By ethnicity, more white teens smoke than any other ethnic group. White teens also have higher percentages that do not plan to quit at all or are delaying the intent for several years.

A pattern of depressed teens smoking compared to other teens does not surface. For example, 22% of teens that smoke one to two packs daily often feel life is not worth living, while 18% who smoke a pack or less a week often feel life is not worth living, compared to 36% that never feel life is not worth living. Of teens that only plan to complete 9th grade, 25% smoke one pack daily. Of teens who plan to complete 12th grade 5% smoke one pack a day, and 66% of teens that plan to complete 10th grade do not smoke compared to 79% of college bound teens who do not smoke.

In response to the question, "Does marijuana smoke contain more cancer causing agents than tobacco smoke?" 66% of white, 56% of black, and 44% of hispanic teens answered correctly.

Substance Abuse

The following provides self-reported information from teens on their behavior and attitude regarding drugs and alcohol: 25% of Delaware's teens report drinking. By gender, 31% of boys and 22% of girls drink. The percentages of drinkers among boys double from 8th to 9th grade, while in girls the percentages double one year later. Five or more drinks in one day is consumed by 6% of the teens. Drinking alcohol and consuming other drugs are risk taking behaviors that have numerous implications: 12% and 10% of boys and girls respectively report using alcohol in concert with other drugs. For girls, a sixfold increase occurs from 8th to 9th grade, and then a steady increase through 12th grade. Among boys, almost 10% of 8th graders report using alcohol with other drugs, compared to 20% of seniors.

Motor Vehicles

Driving or riding under the influence of alcohol and/or other drugs is reported by 21% of the teens. Almost 25% of the teens that often drive or ride under the influence often feel life is not worth living. Of those that never ride or drive under the influence, 56% never feel life is not worth living.

Seat belt use needs to begin before a person learns to drive a car. In Delaware, 60% of teens report not always wearing a seat belt. There is an alarming difference in usage between boys and girls. Among boys, 67% report not always wearing a seat belt compared to 53% of girls. The data indicates that driver's education class may have an impact on seat belt use, although this survey data alone could not prove such a point. Unfortunately, teens appear to revert to old habits later on (ie, large percentages of 11th and 12th graders report not wearing seat belts). A correlation between depression and seat belt use did not surface in this study. Ten percent of teens that always wear a seat belt and 13% that never wear a seat belt often feel life is not worth living. Fifty percent that always wear a belt never feel life is not worth living, compared to 55% who never wear a belt and never feel life is not worth living.

Stress/Depression

Stress is a term that has been used rather loosely. Not all stress is negative, and teens in particular need information and skills in recognizing negative stress and how to decrease and/or ameliorate it. This particular study determined stress by combining responses to the following questions:

1. In the past six months, have you had feelings that life was not worth living?
2. Do you have friends or relatives that you can turn to for help when something is troubling you?
3. Have you lost more than five pounds in the last few months without dieting?
4. Do you usually get enough sleep and feel rested in the morning?

According to this study, 22% of Delaware's teens are highly stressed 25% of Sussex County teens, compared to 22% of Kent County and 21% of New Castle County teens are stressed. Statewide and

in all three counties twice as many girls report being stressed as boys. Ten percent of teens state they often feel life is not worth living. Of the girls and boys, 13% and 6% respectively state frequently they feel life is not worth living. A close look at the data reveals the older the girl, the smaller the percentage feel life is not worth living; however, among boys the responses fluctuate. By ethnicity, 9% of white, 12% of black, 12% of hispanic, and 23% of Asian teens often feel life is not worth living. Thirteen percent of teens who plan to graduate high school and 9% who plan to go to college report feeling life is not worth living, compared to 25% who plan to only complete 8th or 9th grade.

Of girls and boys respectively, 30% and 26% feel they usually do not get enough sleep and feel rested in the morning. The older the teen, the larger the percentage reporting they do not feel rested in the morning. When something is troubling them, 72% and 74% of boys and girls respectively state they have friends or relatives to turn to. Basically, the older the teen, the larger the number who feel they have someone to turn to for help. Teens planning to graduate high school or college had a similar percentage reporting they had no one to turn to than teens with lower academic goals.

Of those teens who often or sometimes feel life is not worth living, 35% often use drugs, and 27% that sometimes feel life is not worth living sometimes use drugs. Fifty-five percent of teens who do not drink never feel life is not worth living, whereas 18% that report very heavy drinking often feel life is not worth living.

Conclusion

In sum, Delaware's adolescents have certain health risks that could be improved by changes in both knowledge and behavior. Early education and prevention strategies can have a tremendous impact on reducing or ameliorating potentially dangerous conditions. A number of chronic conditions can be prevented by not adopting certain behaviors (or quitting early on). The adolescent population deserves attention and education. By educating teens and preteens, many preventable conditions could be avoided.

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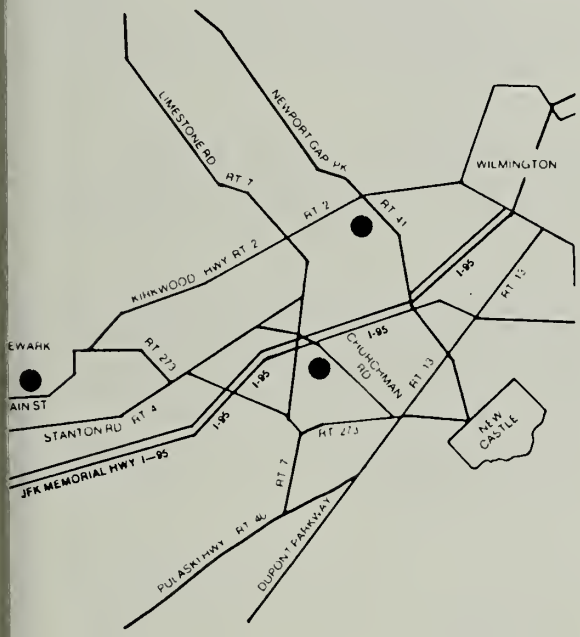

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R. Technician	X-Ray Technician
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rse Practitioner	Scrub Nurse
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For details in enrolling in the CNA Program, AAW Physician Plans, Inc. is working with these local Professional Liability Representatives.

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MODERATOR: Bernard L. Segal, M.D.

3:00-3:30 Yes - Henry S. Sawin, M.d.

3:30-4:00 No - Mark S. Hochberg, M.D.

4:00-5:00 Case presentations - Thach N. Nguyen, M.D.
Panel discussion - James L. Hughes, M.D.,
Ami S. Iskandrian, M.D., Ancil Jones, M.D.,
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SMOKING IN DELAWARE: ECONOMIC COSTS AND DEATHS ATTRIBUTABLE TO CIGARETTE SMOKING IN THE STATE, 1985

Fred N. Breukelman
Paul S. Zeitz, D.O.
Thomas E. Novotny, M.D.

Introduction

This study estimates the state's health costs and mortality which can be attributed to cigarette smoking. In 1985, the most recent year for which statistics are available, a total of 835 smoking-attributable deaths occurred in Delaware. This represents 15% of all deaths in the state. These deaths caused a loss of 9,944 years of potential life.

The total estimated economic cost of smoking in Delaware during 1985 was $148.4 million. About 47% of that cost, or an estimated $69.5 million, was spent on hospitalization and other direct health care costs. Direct costs are expenses for the prevention, diagnosis, and treatment of smoking-related diseases.

Indirect mortality costs, such as lost wages and decreased productivity caused by premature death due to smoking cost the state an estimated $51.3 million during 1985. Indirect morbidity costs, which are lost wages and decreased productivity due to smoking-related disability and disease, were estimated at $27.6 million for the year.

Finally, the report estimates that 15 perinatal deaths occurred in Delaware during 1985 as a result of maternal smoking during pregnancy.

Methodology

Estimates presented in this report were generated by the Smoking Attributable Mortality, Morbidity, and Economic Costs (SAMMEC) computer software program developed by the Minnesota Department of Health's Center for Nonsmoking and Health.[1] The SAMMEC software incorporated the most advanced methodologies available from the fields of epidemiology and health economics to estimate smoking-attributable mortality, years of potential life lost (YPLL), direct health care costs, indirect mortality costs, and indirect morbidity costs.

Smoking-attributable mortality and YPLL estimates were calculated by using the smoking-attributable fraction (SAF) formula.[2] Weighted relative risk estimates from studies of smoking-related diseases, and current and former smoking prevalence estimates are used to derive the SAF.[3] The YPLL estimates were first calculated using age 65 as an endpoint, and then calculated using life expectancy. Mortality from cigarette smoking is largely premature mortality, and the YPLL calculation is a method of showing the extent of premature death.[4]

State-specific smoking prevalence data was derived from the 1985 Current Population Survey of the United States.[5] This data was corroborated by a 1984 survey on smoking prevalence conducted for the Division of Public Health by the University of Delaware Household Survey.[6] Mortality data were obtained from the National Center for Health Statistics "Advanced Report of Final Mortality Data, 1985."[7]

Disease categories used in SAMMEC are infectious (tuberculosis), cardiovascular, respiratory, neoplastic, and digestive diseases (ulcers). Smoking-attributable disease impact on children less than one year old is due to smoking by mothers during pregnancy;[8] the disease categories include short gestation/low birth weight, respiratory distress syndrome, respirato-

Mr. Breukelman is Director of Public Health Education, Division of Public Health, Department of Health and Social Services.

Dr. Zeitz is a resident at the Hospital of the Philadelphia College of Osteopathic Medicine. During the timeframe cited in this article, he was a student intern at the Office on Smoking and Health, Centers for Disease Control, Rockville, Maryland.

Dr. Novotny is on staff at the Office of Smoking and Health, Centers for Disease Control, Rockville, Maryland.

ry conditions of the newborn, and sudden infant death syndrome.

The costs of smoking-attributable illnesses were estimated using the methodology of Rice.[3] First, total health care cost estimates were calculated using the U.S. Health Care Financing Administration's 1982 state cost distribution data for Delaware,[9] adjusted to 1985 levels.[10] These totals were used to calculate smoking-attributable fractions of direct medical costs. Expenses for the diagnosis, treatment, and prevention of smoking-related diseases were estimated by taking data on relative rates of hospital and physician utilization from the National Health Interview Survey of 1980.[11]

We also estimated indirect costs. These values were calculated by using National Center for Health Statistics estimates for the present value of future earnings, discounted at 6%, based on life expectancy and stratified by gender.[3]

Details of the SAMMEC Study

In 1985, Delaware deaths in the selected disease categories totaled 2,635. Of these, 835 are estimated to be smoking-attributable deaths. This represents 15% of the 5,475 total deaths for Delaware in that year. Of these, 272 (33%) smoking-attributable deaths occurred before age 65.

Lung cancer and other neoplasms accounted for 350 smoking-attributable deaths. Another 302 deaths were from the ischemic heart disease and other cardiovascular disease categories. Smoking-related respiratory diseases claimed 170 lives, and 13 deaths were estimated to have been caused by smoking-related ulcers.

The 835 smoking-attributable deaths in Delaware during 1985 were responsible for an estimated 9,944 years of potential life lost, based on an average life expectancy for the United States. On average, this represents 12 years of life lost for each premature death due to smoking. In addition, it should be remembered that smoking-related illnesses tend to be long term, chronic diseases which cause a great deal of suffering and expense prior to premature death.

Because of the small size of Delaware's population and the small number of infant deaths, the SAMMEC estimates regarding perinatal death may not be as accurate as the estimates for the overall adult population. However, applying the program to smoking-related causes of perinatal death nevertheless dramatically demonstrates the risks of maternal smoking during pregnancy. In 1985, this resulted in an estimated 15 perinatal deaths in Delaware. This represents about 18% of the total 82 deaths from the previously listed disease categories. These preventable deaths resulted in 1,110 years of potential life lost, or 74 years per death.

The total economic liability in Delaware due to tobacco smoking is estimated to be $148.4 million for 1985. Hospitalization and other direct health care costs make up about 47% of that total, or $69.5 million. Hospitalization costs were $50.1 million, physician services accounted for $8.6 million, nursing home care for $7.6 million, and medications for $3 million. The remainder of the costs were from professional services.

Indirect mortality costs were estimated at $51.3 million, and indirect morbidity costs at $27.5 million in 1985. More than 40% of the indirect mortality costs, or $20.9 million, were due to lung cancer.

The smoking prevalence rate for adults in Delaware during 1985 was 31.97%. This should be compared to the national adult prevalence rate for 1985 of 28%. While nearly 32% of our population still smokes, another 25% are former smokers, and 43% of the population has never smoked tobacco on a regular basis.

Conclusion

Given the health and economic costs of smoking as estimated in this study, the smoking prevalence rate in our state is alarming. Clearly, the impact of smoking on the health and economy of Delaware requires additional measures to reduce cigarette consumption and to prevent new users.

Several studies, including "A Statewide Adolescent Health Study," conducted by the Division of Public Health's Adolescent Health Program in 1987 (and summarized elsewhere in this issue), indicate that more young girls are smoking than boys.[12] Low birth weight and prematurity, which are responsible for a substantial percentage of perinatal deaths, can be caused by maternal smoking during pregnancy. Because of the risks of maternal smoking during pregnancy, the increasing rate of smoking among women is especially alarming, and special attention needs to be

focused on education to prevent new female smokers.

Nicotine, a drug found in all forms of tobacco, is addicting;[13] and cigarette smoking, which kills more than 300,000 Americans each year,[14] is the nation's largest drug problem. These are facts which often go unmentioned in educational programs because tobacco is still relatively socially acceptable. Because tobacco is so addictive, smoking cessation programs have a high failure rate. We strongly encourage innovation and research in methods of breaking tobacco and other addictions. Research summarized in recent Surgeon General's reports also indicates that multiple interventions seem to be more effective than single interventions. Examples might include combining smoking cessation classes with prescription nicotine gum regimens, stress management, or with meditation or hypnotism.

The economic, social, and health costs of smoking in Delaware are inexcusable. We hope that physicians, other clinicians, public health providers, health policy makers, and the media will use these data to improve their understanding of the relative impact of smoking compared with other causes of premature death. The prevention and treatment of smoking and nicotine addiction must be a high priority public health issue in Delaware, so that our citizens can lead longer, healthier, and more productive lives.

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Editorials

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FROM THE OBVIOUS TO THE OPTIONAL

In setting forth our concepts of the *Delaware Medical Journal* let me start with the obvious and work toward the optional. It seems very clear that the *Delaware Medical Journal* is the official publication of the Medical Society of Delaware. As such it should tell us how and what the Medical Society of Delaware is doing, not only in the Proceedings of the Annual Meeting and the President's page, but also what issues are absorbing the time and interest of our leadership, what position the Society is officially taking on issues confronting medicine, how and why those positions were adopted, and hopefully some of the dissenting minority thinking as well. In other words, in those sections of the *Journal* devoted to the medical society we hope to air the pros and cons of any controversial issues.

But the *Journal* should be more than a newsletter. It should also reflect the practice of medicine and all its specialties as it exists in Delaware, and hopefully, looking ahead to the future, the practice of medicine as we fully hope and expect it should be years hence. This might spotlight deficiencies, might call attention to new thinking, and to new drugs and techniques we should be using in our diagnostic and therapeutic approaches.

We also want to take advantage of the many educational programs conducted throughout our state and publish as many of the best of those presentations as we can. We want to provide opportunities for our bright young new doctors to break into print — to encourage and help them as they develop their writing skills. Finally we want to urge and persuade the fine physicians throughout our state to take a moment to look at what they are doing and report it for the benefit of all of us. This is especially true for the doctors of Kent and Sussex Counties who have excellent high volume practices but are seldom heard from outside their immediate area.

Instead of worrying about a physician glut — which may never develop — we all should rejoice that the shortages of a few years ago (which overworked everyone) are past, and take advantage of any little bit of leisure to tabulate our cases and report our results. The *Delaware Medical Journal* should provide a vehicle for you to do just that. Don't be afraid. Let's hear from you! We want to give you any help you need to make this a truly Delaware medical journal.

E. Wayne Martz, M.D.

THE IMPORTANCE OF PUBLIC HEALTH MEASURES

Nearly all of us, when we were interviewed for admission to medical school, were asked why we wanted to be doctors. Some had thought this through carefully and had good clear-cut reasons. For others (such as me) this may have been the first time we actually tried to list the reasons. For most applicants it boils down to two major reasons: first, we enjoy sciences, and second, we want to help people. For some, who came to an interest in medicine via an interest in sociology, the first of these may not have been true, but I firmly believe that the desire to help mankind was universally true. In fact, if you didn't voice this in your response to the question, you probably didn't get an acceptance. This was one of the selection criteria. So we set about learning all that was needed to take care of patients and help people.

In my case, it wasn't until years later that some synapse in an obscure corner of my brain finally closed and I realized that no disease that I am aware of has ever been conquered by finding a cure for it. Isoniazid has not eliminated tuberculosis, nor has penicillin eliminated pneumonia or syphilis. The public wants us to find "a cure for cancer," (whatever that is), but you can rest assured that when and if that magic bullet is ever found, it will not eliminate cancer.

On the other hand many diseases have been very well controlled *without* finding a cure — rabies, typhoid, yellow fever, malaria, to name a few. In fact, the only disease that has ever been total-

ly eliminated still does not have a cure, and that of course is smallpox. If one were to catch it today, medical science has little to offer beyond good nursing care and prayer.

The point is that if we truly want to help mankind probably the most effective way to do it is through public health measures. Treating individual patients, though very satisfying to both doctor and patient, hardly makes a dent in the overall death rate. There is little or no correlation between the amount that a nation spends on medical care and the health and longevity of its populace. Even changes in infant mortality, which produce most of the dramatic changes in life expectancy — are greatly dependent on public health measures such as education of teenagers and case finding procedures to get pregnant women into good prenatal care. Else why does Delaware, with excellent obstetricians and outstanding pediatrics and neonatology, have one of the worst records in the nation for infant mortality?

Most thoughtful doctors who sincerely want to have an impact on the health of their communities do not come to a realization of these things until they are well launched into a career in one or another standard specialty. Then it is usually too late to go back and start over. Most of the doctors in public health careers indeed started out in one or another of the common specialties. In the case of Dr. Olsen it was Pediatrics. But then, often at considerable personal sacrifice, they do bite the bullet and go back and make the change. We owe them a great debt of gratitude, because they are the ones who make us all look good. We need more of them, and we need to be sure they are treated well, rewarded, given what they need to do the job. This issue of the *Delaware Medical Journal* is dedicated to Dr. Lyman Olsen and his team.

E. Wayne Martz, M.D.

PUBLIC HEALTH FOR PUBLIC GOOD

It is somewhat paradoxical that during this time of increased interest in health promotion, disease prevention, and increased involvement by medical societies and individual physicians in public health concerns, that medical schools are systematically removing Departments of Public Health from their structure. Some years back when physician shortages were forecast, the departments were reorganized into Departments of Primary Care or Family Practice.

I must admit that public health as taught in my medical school days, was the least interesting and

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probably worst taught subject matter in the curriculum, usually taught by teachers drafted from other departments. I must also admit that many health departments were held in low esteem.

It is interesting to observe that during this same period, the number of identified schools of public health (separate graduate programs) has increased from 17 to 23, and a number of other major programs in occupational health and medicine have evolved.

The field of public health has changed rapidly, as has medicine in general, and schools of public health are examining their curricula and teaching methods as well as becoming heavily involved in community programs.

Those who are untrained or ill-informed on public health often see the discipline as an enemy, a regulator, and a competitor in the medical profession. On the other hand, those who have had appropriate exposure to public health through graduate training, rotation through public health programs in residency, or involvement in committees, task forces, etc, see us as partners in the prevention of disease and in efforts to control costs. Public Health can be the mechanism for community involvement, setting appropriate standards, monitoring success of efforts, identifying potential patients, assisting in the care of the poor and needy, and keeping eyes focused on the serious problems confronting communities.

In this issue, a wide range of activities will be addressed which shows the ubiquitous character of the agency. Indeed, public health affects every individual in the state on an almost daily basis. The mission of our Division is to prevent disease, promote health, protect the population from environmental health hazards, and provide care for vulnerable populations.

To carry out this mission, it is imperative that we work with all professional groups and that our programs operate with high standards of efficiency so that we indeed assist in solving problems, not creating them.

Lyman J. Olsen, M.D., M.P.H.

SPOTLIGHT ON THE GUEST EDITOR: LYMAN J. OLSEN, M.D.

Dr. Olsen began his public health career in 1968, after ten years of pediatric practice. Following a year at the University of California at Berkeley, where he received his M.P.H. degree with a specialty in Maternal and Child Health and Crippled Children's Services, he returned to his native state of Utah and assumed the position of Director of Maternal and Child Health. This was followed by additional duties involving alcoholism programs, CCS, nutrition, and speech pathology/audiology.

In 1970, Dr. Olsen assumed the position of Director of the Utah State Division of Health, a position he held for nine years. He left Utah to take on more clinical activities as Chief of CCS and Medical Director of the Arizona Children's Hospital. In 1980, Dr. Olsen accepted a position in international health as Chief of Party of an advisory team to the Ministry of Health, Arab Republic of Egypt, in an attempt to improve maternal and child health in the five most populated areas of Cairo, Egypt.

In 1982, he returned to the United States and took his current position as Director of the Delaware Division of Public Health. In that position, he serves on the State Board of Health, the Inland Bays Task Force, the Inland Bays Monitoring Committee, the Health Care Cost Management Commission, the Statewide Health Coordinating Council, Chairman of the Infant Mortality Task Force, and Chairman of the AIDS Advisory Task Force.

Dr. Olsen has also served as President of the Delaware Public Health Association, Chairman of the Executive Committee for the Handicapped Child of Delaware, Inc., on the Board of Directors of the March of Dimes, and other professional service committees, and is serving on the Executive Committee of the American Lung Association of Delaware, where he serves as affiliate representative to the National Board.

Dr. Olsen has been National President of the Conference of State and Province Health Association of North America, Association of State and Territorial Health Officers, and is presently Chairman of the Board of Public Health Foundation of Washington, D.C. He has also served as Chairman of Maternal and Child Health Section of the American Public Health Association, and on the Governing Council of that group. He also serves on the National Advisory Council on Improved Pregnancy Outcomes and the National Immunization Policy Committee. Dr. Olsen has received awards from the Utah Public Health Association, USMA, and ASTHO.

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Thomas Creer, Ph.D.
Chair, Department of
Psychology

Elliot Ellis, M.D.

9:15 a.m. Epidemiology Of Childhood Asthma Including Asthma Mortality

10:05 a.m. New Insights Into The Pathophysiology Of Asthma With Emphasis On Therapeutic Implications

Thomas Creer, Ph.D.

1:15 p.m. The ABC's Of Self-Management For Childhood Asthma

4:00 p.m. Critique Of Studies On Behavioral And Psychological Responses Attributed to Theophylline Usage By The Childhood Asthmatic

Robert Kettrick, M.D.

11:10 a.m. Intensive Management of Status Asthmaticus

Raj Padman, M.D.

11:45 a.m. Gastroesphageal Reflux and Recurrent Pulmonary Disease

Andrew Weinstein, M.D.

12:20 p.m. Medical Management Of Crying-Induced Asthma: A Child-Parent Psychosomatic Syndrome

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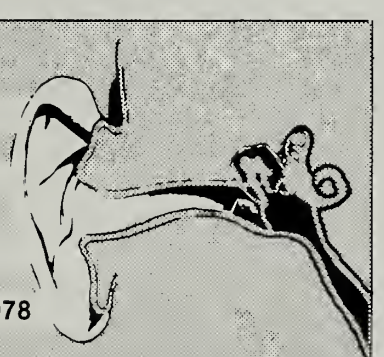

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Medical Ethics

COMMITTEE ON ETHICS

This material has been developed by the Medical Society of Delaware's Committee on Ethics, Robert W. Frelick, Chairman.

In discussion of medical ethics, individual solutions are often sought without considering society's needs. This is the basis for many of the disagreements about testing for HIV. Concern about individual rights can easily lose sight of bigger issues. How can individual interests be balanced against what is best for a family or society in general? Contrariwise, fear of the implications for society may constrict individual choices: For example, fear that the termination of life support in one individual might lead to a general justification for euthanasia. At the same time, society in general ignores the cynical breach of ethics associated with the profits made at the expense of the human suffering of 350,000 deaths/year by those legally promoting the sale of cigarettes. It is even more distressing to note that their promotion is with the connivance of government. Changes in attitudes about smoking over the last ten to fifteen years have switched from the right to smoke to the right to breathe air free of tobacco smoke. What is "right" in one situation and time may in another situation be considered unethical. Many ethical decisions obviously cannot be "written in stone." Often there is no right or wrong. This is why a physician who is seeking the optimum therapeutic benefit for a patient frequently is in the best position to resolve ethical issues without recourse to outside legal or ethical opinions.

As physicians we should not abdicate our responsibilities to resolve individual problems. We should ask for consultations when necessary. Society's ethical problems likewise need multiple opinions, especially from those in the legal profession, in legislatures and even in ethical think tanks. Can the suffering of those unable to afford medical care or the withholding of pain medication from end stage disease patients be ignored?

Too many ethicists worry about problems which seldom occur in real life. An example of this has been the rush to discuss use of fetal tissue to help Parkinson's disease when the latest data suggest that improvements associated with that particular technique are not reliable, so that the real concern should be about using an unproven technique rather than the use of fetal tissue.

Let us set an example for the resolution of many of society's ethical problems by how we help our patients manage their ethical concerns. The Medical Society of Delaware has organized a Committee on Ethics to provide the members with medical opinions and insights from multiple disciplines when additional help is desired. The Committee stands ready to respond to your requests with the understanding that the Committee will not render a legal opinion and that final decisions remain with individual responsible physicians and their patients.

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DELAWARE MEDICAL JOURNAL INDEX
SUBJECT

NOTE: Because of the special nature of the August issue of the *Delaware Medical Journal* (a joint issue with the *Delaware Lawyer),* it is not included in the consecutive number system reflect throughout Volume 60. The index includes the following notation for the August issue: Aviii.

-A-

Abortion in Adolescence: A Clinician's Reflections
Tomas J. Silber, M.D., M.A.S.S. ix 487
About the Cover (Pediatrics) vi 247
Acceptance of Maternal Alpha-Fetoprotein Screening in Wilmington Hospital's Obstetrical Clinic
Karen Byrne-Essif, M.S.
John Naber, M.S.
Garrett H.C. Colmorgen, M.D. x 569
Accessory Figures from *Tabulae...* (BW) v 329
Advertising and HMOs (5.20) (ME) v 317
Advertising and Publicity (5.01) (ME) iii 181
AIDS as an Occupational Disease: Whose Right to Know?
Lawrence Gostin, Esq. ix 479
AIDS: Designing a Balanced Legislative Response
Barry Ray Furrow, Esq. Aviii 51
AIDS Hysteria in Delaware (E)
Diana Dickson-Witmer, M.D. ix 528
Allowing the Dying to Die (ME)
H. Robert Silverstein, M.D. x 579
AMA House of Delegates, Delegate's Report: 1987 Interim Meeting of the
Daniel A. Alvarez, M.D. iii 201
AMA House of Delegates, Delegate's Report: 1988 Annual Meeting of the
Daniel A. Alvarez, M.D. x 597
Amplification (E)
Bernadine Z. Paulshock, M.D. x 587
Anatomy of an Adult Woman (BW)
Leonardo da Vinci ii 89
Annual Review of Immunology, Vol 5 (BR)
Mark A. Marsili, Ph.D. iv 261
Anti-arthritic Drugs, Research Strategy for the Discovery of, From Computer Modeling to FDA Approval:
Neil Ackerman, Ph.D. xi 665
Arbitration--A Rational Alternative? (PP) v 279
Are We a Self-Serving Group? (PP) i 7

-B-

Bioethical Humor
Dr. Aap ix 519
Book Reviews
Physicians Observed
Carl T. Opderbeck, M.D. ii 127
Soft Tissue Rheumatic Pain: Recognition, Management, Prevention
James H. Newman, M.D. ii 128
Textbook of General Medicine and Primary Care
David Platt, M.D. ii 129
Annual Review of Immunology, Vol 5
Mark A. Marsili, Ph.D. iv 261
Dubois' Lupus Erythematosus
James H. Newman, M.D. iv 261
Sjogren's Syndrome
James H. Newman, M.D. iv 262
Practicing Physician's Approach to Headache, 4th ed
Lawrence J. Markman, M.D. iv 263
Sectional Human Anatomy
Joseph M. Ullman, M.D. iv 265
Breast Cancer: Diagnosis and Treatment
J. Wesley Clayton, III, M.D. vii 459
Pocket Atlas of MRI Body Anatomy
Bernadine Z. Paulshock, M.D. vii 459
Nelson's Textbook of Pediatrics
David Platt, M.D. vii 460
Cardiovascular Anesthesia
Eugene I. Tolpin, M.D. vii 460
Stories of Sickness
David Platt, M.D. vii 461
Disease and Discovery
Jo Ann Rosenfeld, M.D. vii 461
Changing Humors of Portsmouth
Norman L. Cannon, M.D. vii 462
Control of Communicable Diseases in Man, 14th Ed
Gloria C. Fong, M.D. vii 464
Clinimetrics
Brian M. Willard x 611
Hematology: The Blossoming of a Science
David Platt, M.D. x 612
Systemic Lupus Erythematosus
James H. Newman, M.D. x 613
Clinical Concepts in Regional Musculoskeletal Illness
James H. Newman, M.D. x 613
Overcoming Breast Cancer
Tammi D. Davis, M.D. x 614
Rhythm Quizlets - Self Assessment
James M. Hofford, M.D. x 615

Botanic Physician, John A. Brown
Everett D. Bryan, M.D. x 559
Breast Cancer: Diagnosis and Treatment (BR)
J. Wesley Clayton, III, M.D. vii 459
Bush and Dukakis on Health and Related Topics, Where They Stand vii 447

-C-

Cardiac Doppler Echocardiography Principles and Applications
Christopher H. Wendel, M.D. v 285
Cardiovascular Anesthesia (BR)
Eugene I. Tolpin, M.D. vii 460
Care of the Brain Dead and Other Troubling Patients (E)
Thomas S. Vates, Jr., M.D. ix 529
Catholic Perspective on Religion and Organ Transplantation, A
Thomas R. Ulshafer, S.S., Ph.D. ix 505
Cellulitis, Recurrent Perianal Streptococcal
Ricardo Castro, M.D.
Jaime Rivera, M.D. vii 421
Certificates, New Birth and Death
Michael L. Richards xii 726
Changing Humors of Portsmouth (BR)
Norman L. Cannon, M.D. vii 462
Cheers for Dr. Spear (E)
Bernadine Z. Paulshock, M.D. iii 198
Choose Life: Jewish Tradition and Organ Transplantation
Kenneth S. Cohen ix 509
Clinical Concepts in Regional Musculoskeletal Illness
James H. Newman, M.D. (BR) x 613
Clinician's Reflections, Abortion in Adolescence:
Tomas J. Silber, M.D., M.A.S.S. ix 487
Clinimetrics
Brian M. Willard (BR) x 611
Closed Head Injuries in Children, Management of
Michael Alexander, M.D. iii 165
Collaboration with *Delaware Lawyer* (PP) Aviii 5
Commitment to Hope, A
John F. Maguire Aviii 46
Common Diagnostic Tests: The Book and the Problem (E)
Bernadine Z. Paulshock, M.D. v 323
Computerized Health Risk Appraisal
Fred N. Breukelman xii 717
Computers, Confidentiality: (5.07) (ME) ii 77
Confidentiality (5.05) (ME) iv 245
Confidentiality: Computers (5.07) (ME) ii 77
Congenital Heart Defects, Open Heart Surgery for: Overview and Review of the Early Experience at the Medical Center of Delaware
Kathleen W. McNicholas, M.D.
Jorge Serra, M.D.
N. Peter Karmilowicz, M.D.
Paschal M. Spagna, M.D.
Gerald M. Lemole, M.D. vii 413
Considerations and Potential Pitfalls in Lab Tests for AIDS
Cyril J. Wecht, Esq. Aviii 27
Control of Communicable Diseases in Man, 14th Ed (BR)
Gloria C. Fong, M.D. vii 464
Cover
Pediatrics
Douglas Bugel iii
"Crack" in the Emergency Door, The (E)
Daniel G. Sayers, M.D. v 235
Current Management of Spontaneous Pneumothorax
Festus B. Dada, M.D.
Allen L. Davies, M.D. i 17

-D-

Death of Benjamin Rush, The (E)
Bernadine Z. Paulshock, M.D. i 32
Deaths
Guido Ascanio, M.D. ii 132
Francis Godwin, M.D. ii 132
Charles M. Moyer, M.D. ii 132
Martin B. Pennington, M.D. iii 203
Walter L. Bailey, M.D. iv 259
Harry A. Carl, M.D. iv 259
F.B. Lane Haines, M.D. vii 441
Philip Reed Walker, M.D. ix 535
George J. Boines, M.D. ix 535
Elton Resnick, M.D. x 603
Ervin L. Stambaugh, M.D. x 603
Donald F. Coburn, M.D. xi 687
Homer M. Kimmich, M.D. xi 687
Lester A. Bronheim, M.D. xi 687
Delaware
Prescribing Habits of Delaware's Physicians (E)
Bernadine Z. Paulshock, M.D. ii 84
WVMI PRO and Delaware Physicians, The
William H. Duncan, M.D. iii 145
Evolution of Pediatrics in Delaware, The (E)
Michael L. Spear, M.D. iii 185
Delaware Is in Touch (L)
Lucille P. Siegel, M.P.H. iv 255
State of Peer Review in Delaware Today, The (SR)
Victor F. Battaglia, Esq. iv 231
AIDS Hysteria in Delaware (E)
Diana Dickson-Witmer, M.D. ix 528
Delaware Psychiatry Circa 1988 (E)
Cathryn Clary, M.D.
Edward Schweizer, M.D. x 587
Ronald McDonald House for Delaware, A (PP) x 551

Delaware Is in Touch (L)
Lucille P. Siegel, M.P.H. iv 255
Delaware Psychiatry Circa 1988 (E)
Cathryn Clary, M.D.
Edward Schweizer, M.D. x 587
Delaware State Tumor Registry
Allan Topham xii 714
Delaware's Bureau of Environmental Health
Lawrence J. Krone, Ph.D., M.P.H. xii 713
Delaware Statewide Adolescent Health

Study-1987
Lucille P. Siegel, M.P.H. xii 727
Delegate's Report: 1987 Interim Meeting of the AMA House of Delegates
Daniel A. Alvarez, M.D. iii 201
Delegate's Report: 1988 Annual Meeting of the AMA House of Delegates
Daniel A. Alvarez, M.D. x 597
Department of Justice: Dealing with a Constellation of Problems
David J. Lyons, Esq. Aviii 71
Development Delay in High Risk Infants, A Multidisciplinary Approach to
Nidia de Yanez, M.D. iii 159
Diagnosis and Prevention of Bilateral Gluteal Hypermalacia Atrophicans Syndrome (Or Gallup Poll Disease), On the (E)
Maurice Liebesman, M.D. iv 250
Diagnosis of Thoracic Outlet Syndrome (L)
Barry E. White, M.D. x 606
Dilemma of the Nursing Shortage, The
John M. Levinson, M.D. iv 223
Disease and Discovery (BR)
Jo Ann Rosenfeld, M.D. vii 461
Division of Public Health, The
Lyman Olsen, M.D., M.P.H. xii 705
Dr. Albert Ottow: Masterful Inactivity and Dying with Dignity (L)
William T. Hall, M.D. iv 257
Doctor-Patient Arbitration: A Proposal Whose Time Has Come (SR)
Francis S. Babiarz
Phillip B. Bartoshesky
Victor F. Battaglia
Jeffrey S. Martin
Wayne A. Marvel
Roger Sanders
Mary Pat Trostle v 301
Doctor's Dilemma, Therapy of Peptic Ulcer Disease: The (E)
Harris R. Clearfield, M.D. vii 443
Doctrine of Informed Consent, Medical Legal Case Conference: The
David E. Raskin, M.D. v 313
Does Anyone Remember?, Integrating the Delaware Hospital: (E)
Bernadine Z. Paulshock, M.D. iv 248
Dover or Bust (PP) ii 67
Dubois' Lupus Erythematosus (BR)
James H. Newman, M.D. iv 261
Dukakis (and Bush) on Health and Related Topics, Where They Stand: vii 447
DuPont Company's Decision, The, Saving Our Ozone Layer: (E)
Bernadine Z. Paulshock, M.D. ix 533

-E-

Early Detection: The Role of the Dentist
Gerald Cioffi, D.D.S., M.S. Aviii 10
Early Experience at the Medical Center of Delaware, Open Heart Surgery for Congenital Heart Defects: Overview and Review of the
Kathleen W. McNicholas, M.D.
Jorge Serra, M.D.
N. Peter Karmilowicz, M.D.
Paschal M. Spagna, M.D.
Gerald M. Lemole, M.D. vii 413
Echocardiography Principles and Applications, Cardiac Doppler
Christopher H. Wendel, M.D. v 285
Editorials
National Cholesterol Education Program
Michael F. Stillabower, M.D. i 29
Industrial Medicine and Community Doctors
William D. Shellenberger, M.D. i 30
Death of Benjamin Rush, The
Bernadine Z. Paulshock, M.D. i 32
Negligence in Psychiatric Practice
V. Terrell Davis, M.D. ii 81
Prescribing Habits of Delaware's Physicians, The
Bernadine Z. Paulshock, M.D. ii 84
Spotlight on the Guest Editor iii 185
Evolution of Pediatrics in Delaware, The
Michael L. Spear, M.D. iii 185
Role of Subspecialists in a Community Practice Setting, The
Robert A. Doughty, M.D., Ph.D. iii 186
Pediatric Intensive Care
Michael E. Norman, M.D. iii 188
Handicapped Children: There is Progress!
Ted E. Chronister, M.D. iii 190
You've Come a Long Way, Pediatrics
Maurice Liebesman, M.D. iii 195
Pediatric Nursing: Lessening the Emotional Trauma
Jacqueline W. Levett, R.N., M.S.N. iii 196
Cheers for Dr. Spear
Bernadine Z. Paulshock, M.D. iii 198
Pendulum's Arc: A Lesson for Today's Physician, The
Edward R. Sobel, D.O. iv 247
Integrating the Delaware Hospital: Does Anyone Remember?
Bernadine Z. Paulshock, M.D. iv 248
On the Diagnosis and Prevention of Bilateral Gluteal Hypermalacia Atrophicans Syndrome (Or Gallup Poll Disease)
Maurice Liebesman, M.D. iv 250
Is Courtesy Old Hat?
Carl I. Glassman, M.D. v 321
Common Diagnostic Tests: The Book and the Problem
Bernadine Z. Paulshock, M.D. v 323
"Crack" in the Emergency Room Door, The
Daniel G. Sayers, M.D. v 325
Introduction: The Newest Specialty
Herbert J. Keating, III, M.D. vi 389
Taking Care of the Well Elderly
Herbert J. Keating, III, M.D. vi 389
Gray Boomers, The
Bernadine Z. Paulshock, M.D. vi 393
State of the Art, The
Alvan R. Feinstein, M.D. vi 394

Primary Care: New Patterns of Training
David Platt, M.D. vii 443
Therapy of Peptic Ulcer Disease: The Doctor's Dilemma
Harris R. Clearfield, M.D. vii 443
Medical Ethics: A Rediscovered Discipline
Maurice Liebesman, M.D. ix 475
Informed Consent: An Ethics Question?
Robert W. Frelick, M.D. ix 523
AIDS Hysteria in Delaware
Diana Dickson-Witmer, M.D. ix 528
Care of the Brain Dead and Other Troubling Patients
Thomas S. Vates, Jr., M.D. ix 529
Quandaries in Reproductive Technology
Jeffry I. Komins, M.D. ix 530
Medical Need and the Private Practice Physician
David Platt, M.D. ix 532
Saving Our Ozone Layer: The DuPont Company's Decision
Bernadine Z. Paulshock, M.D. ix 533
Plague Politics
William E. Wiggin, Esq. Aviii 41
Posttransfusion Hepatitis
Jane Straughn, M.D. x 585
Amplification
Bernadine Z. Paulshock, M.D. x 587
Delaware Psychiatry Circa 1988
Cathryn Clary, M.D.
Edward Schweizer, M.D. x 587
Long Term Care: What Does It Cost?
Edward R. Sobel, D.O. x 591
Should Pharmaceutical Companies Provide CME?
Bernadine Z. Paulshock, M.D. x 592
Introduction - Special Rheumatology Issue
James H. Newman, M.D. xi 679
Omega-3 Fatty Acids in Rheumatoid Arthritis.
Joel M. Kremer, M.D. xi 679
History of the Arthritis Foundation, Delaware Chapter, A
Christopher R. Donoho, Jr., M.D. xi 681
Digitorum Nodi: Little Hard Knobs
Bernadine Z. Paulshock, M.D. xi 683
Editor's Farewell, The
Bernadine Z. Paulshock, M.D. xii 701
From the Obvious to the Optional
E. Wayne Martz, M.D. xii 741
The Importance of Public Health Measures
E. Wayne Martz, M.D. xii 741
Public Health for Public Good
Lyman J. Olsen, M.D., M.P.H. xii 743
Ethical Considerations in Solid Organ Transplants
John Noseworthy, M.D. ix 497
Ethical Guidelines for Professional Advertising (ME) vii 435
Ethics Question, An?, Informed Consent: (E)
Robert W. Frelick, M.D. ix 523
Evolution of Pediatrics in Delaware, The (E)
Michael L. Spear, M.D. iii 185

-F-

Feeding the Low Birth Weight Infant
Mary Lavelle Spear, B.S.N.
Michael L. Spear, M.D. iii 151
Flying Blind: The Insurance of Concealed Risks
Michael J. Bartholomew, Esq. Aviii 62

-G-

Genetics Services in Delaware
Louis E. Bartoshesky, M.D., M.P.H. xii 718
Geriatrics Special Issue
Protected Peer Review (PP) vi 349
Medical Grand Rounds: Old People and Surgery
Herbert J. Keating, III, M.D. vi 351
Renal Function and Disease in the Elderly
Laurence H. Beck, M.D. vi 363
Psychiatry and the Elderly: Diagnosis, Treatment, and Medical/Ethical Dilemmas
David E. Raskin, M.D. vi 371
Thyroid Disorders in the Elderly
William L. Jaffee, M.D. vi 375
Health Care of the Elderly: Infinite Promise in a World of Limited Resources
William V. Roth, Jr. vi 379
Is Medical Ethics a Tradition and Ideal Without a Future? (ME)
Edmund D. Pellegrino, M.D. vi 385
Introduction: The Newest Specialty (E)
Herbert J. Keating, III, M.D. vi 389
Taking Care of the Well Elderly (E)
Herbert J. Keating, III, M.D. vi 389
Gray Boomers, The (E)
Bernadine Z. Paulshock, M.D. vi 393
State of the Art, The (E)
Alvan R. Feinstein, M.D. vi 394
Gray Boomers, The (E)
Bernadine Z. Paulshock, M.D. vi 394
Growing Pains
Robert A. Doughty, M.D., Ph.D. xi 641

-H-

Handicapped Children: There is Progress! (E)
Ted E. Chronister, M.D. iii 190
Health Care of the Elderly: Infinite Promise in a World of Limited Resources
William V. Roth, Jr., vi 379
Hematology: The Blossoming of a Science
David Platt, M.D. (BR) x 612
High Risk Infants, A Multidisciplinary Approach to Development Delay in
Nidia de Yanez, M.D. iii 159
House Concurrent Resolution No. 121 (Special Issue) vii 431
Hopkins, Women Doctors From Johns
Jo Ann Rosenfeld, M.D. ii 73

-I-

In Black and White
View of Lock Hospital, Hyde Park Corner, London i 35
Anatomy of an Adult Woman

Leonardo da Vinci ii 89
Scanning electron micrograph of fescue (lawn grass) pollen x 3000 iv 253
Accessory Figures from *Tabulae...* v 329
Illustrations from William Harvey's *De Mortu...* vii 439
Physician examining infant. x 609
Ilustrations from William Harvey's *De Mortu...* vii 439
Industrial Medicine and Community Doctors (E)
William D. Shellenberger, M.D. i 30
Infinite Promise in a World of Limited Resources, Health Care of the Elderly:
William V. Roth, Jr. vi 379
Informed Consent: An Ethics Question? (E)
Robert W. Frelick, M.D. ix 523
Informed Consent and Confidentiality Regarding HIV Related Tests (SR) Aviii 43
Informed Professional: Another View of HIV Testing, The
Lorraine Day, M.D. Aviii 35
Integrating the Delaware Hospital: Does Anyone Remember? (E)
Bernadine Z. Paulshock, M.D. iv 248
Intermittent Torticollis (VB)
Leslie E. Grissom, M.D. iv 241
Introduction: The Newest Specialty (E)
Herbert J. Keating, III, M.D. vi 389
Is Courtesy Old Hat? (E)
Carl I. Glassman, M.D. v 321
Is Medical Ethics a Tradition and Ideal Without a Future? (ME)
Edmund S. Pellegrino, M.D. vi 385
Isn't Something Missing? (L)
Leon Morton Green, M.D. iv 255
It's Everybody's Job (PP) iii 141

-J-

Jewish Tradition and Organ Transplantation, Choose Life:
Kenneth S. Cohen ix 509
John 15:13: A Protestant's View of Organ Donation
Marlene Walters, Ph.D. ix 513
John A. Brown, Botanic Physician
Everett D. Bryan, M.D. x 559
Johns Hopkins, Women Doctors From
Jo Ann Rosenfeld, M.D. ii 73

-K-

-L-

Laws and Their Importance to Disease Prevention, New
Paul R. Silverman, Dr. P. H.
David E. Wolfe, P.A., R.N., M.P.H. xii 721
Legislative Posture, The
David J. Lyons, Esq. Aviii 79
Letters to the Editor
Isn't Something Missing?
Leon Morton Green, M.D. iv 255
Delaware is in Touch
Lucille P. Siegel, M.P.H. iv 255
Dr. Albert Ottow: Masterful Inactivity and Dying with Dignity
William T. Hall, M.D. iv 257
Taking the Malpractice Crisis into Physician Hands
Stephen R. Permut, M.D. x 605
Diagnosis of Thoracic Outlet Syndrome
Barry E. White, M.D. x 606
Mental Illness Awareness
Robert N. Dumin, M.D. xi 685
Lesson for Today's Physician, The Pendulum's Arc: A (E)
Edward R. Sobel, D.O. iv 247
Long Term Care: What Does It Cost? (E)
Edward R. Sobel, D.O. x 591
Low Birth Weight Infant, Feeding the
Mary Lavelle Spear, B.S.N.
Michael L. Spear, M.D. iii 151
Lyme Disease: A Historical Perspective
James H. Newman, M.D. xi 651
Lung Cancer in Rubber Manufacturing Workers: Two Case Reports
Rosemary K. Sokas, M.D.
Thorne Sparkman, Jr., M.D.
Walter J. Levinsky, M.D. x 573

-M-

Management of Closed Head Injuries in Children
Michael Alexander, M.D. iii 165
Maternal Alpha-Fetoprotein Screening in Wilmington Hospital's Obstetrical Clinic, Acceptance of
Karen Byrne-Essif, M.S.
John Naber, M.S.
Garrett H.C. Colmorgen, M.D. x 569
Medical Classics
Memoire sur la Fermentation Applee Lactique
David Platt, M.D. i 23
Medical Ethics
8.13 Substitution of Surgeon Without Patient's Knowledge i 11
5.07 Confidentiality: Computers ii 77
5.01 Advertising and Publicity iii 181
5.05 Confidentiality iv 245
5.20 Advertising and HMOs v 317
Is Medical Ethics a Tradition and Ideal Without a Future?
Edmund D. Pellegrino, M.D. vi 385
Statement of Physician Advertising vii 433
Ethical Guidelines for Professional Advertising vii 433
Allowing the Dying to Die
H. Robert Silverstein, M.D. x 579
Informed Consent
Robert W. Frelick, M.D. xi 675
Committee on Ethics
Robert W. Frelick, M.D. xii
Medical Ethics: A Rediscovered Discipline (E)
Maurice Liebesman, M.D. ix 475
Medical Ethics in Medical Practice
Robert L. Perkel, M.D. ix 491

Medical Ethics Special Issue
Rx--Physician Political Involvement (PP) ix 411
Medical Ethics: A Rediscovered Discipline (E)
Maurice Liebesman, M.D. ix 475
Informed Consent: An Ethics Question? (E)
Robert W. Frelick, M.D. ix 523
AIDS Hysteria in Delaware (E)
Diana Dickson-Witmer, M.D. ix 528
Care of the Brain Dead and Other Troubling Patients (E)
Thomas S. Vates, Jr., M.D. ix 529
Quandaries in Reproductive Technology (E)
Jeffry I. Komins, M.D. ix 530
Medical Need and the Private Practice Physician (E)
David Platt, M.D. ix 532
Saving Our Ozone Layer: The DuPont Company's Decision (E)
Bernadine Z. Paulshock, M.D. ix 533
AIDS as an Occupational Disease: Whose Right to Know?
Lawrence Gostin, Esq. ix 479
Abortion in Adolescence: A Clinician's Reflections
Tomas J. Silber, M.D., M.A.S.S. ix 487
Medical Ethics in Medical Practice
Robert L. Perkel, M.D. ix 491
Ethical Considerations in Solid Organ Transplants
John Noseworthy, M.D. ix 497
Catholic Perspective on Religion and Organ Transplantation, A
Thomas R. Ulshafer, S.S., Ph.D. ix 505
Choose Life: Jewish Tradition and Organ Transplantation
Kenneth S. Cohen ix 509
John 13:15: A Protestant's View of Organ Donation
Marlene Walters, Ph.D. ix 513
Bioethical Humor
Dr. Aap ix 519
Cover
Provided by Maurice Liebesman, M.D. ix
Medical Grand Rounds
Old People and Surgery
Herbert J. Keating, III, M.D. vi 351
Medical Legal Case Conference: The Doctrine of Informed Consent
David E. Raskin, M.D. v 313
Medical Need and the Private Practice Physician (E)
David Platt, M.D. ix 532
Memoire sur la Fermentation Applee Lactique (Medical Classics)
David Platt, M.D. i 23

Minority Report of the AIDS Advisory Task Force
Diana Dickson-Witmer, M.D. Aviii 81
Multidisciplinary Approach to Development Delay in High Risk Infants, A
Nidia de Yanez, M.D. iii 159

-N-

National Cholesterol Education Program (E)
Michael F. Stillabower, M.D. i 29
Negligence in Psychiatric Practice (E)
V. Terrell Davis, M.D. ii 81
Nelson's Textbook of Pediatrics (BR)
David Platt, M.D. vii 460
New Patterns of Training, Primary Care: (E)
David Platt, M.D. vii 443
Newest Specialty, The: Introduction (E)
Herbert J. Keating, III, M.D. vi 389

-O-

Maternal Alpha-Fetoprotein Screening in Wilmington Hospital's Obstetrical Clinic, Acceptance of
Karen Byrne-Essif, M.S.
John Naber, M.S.
Garrett H.C. Colmorgen, M.D. x 569
Occupational Disease: Whose Right to Know?, AIDS as an
Lawrence Gostin, Esq. ix 479
Old People and Surgery, Medical Grand Rounds
Herbert J. Keating, III, M.D. vi 351
On the Diagnosis and Prevention of Bilateral Gluteal Hypermalacia Atrophicans Syndrome (Or Gallup Poll Disease) (E)
Maurice Liebesman, M.D. iv 250
Oncology, Pediatric: The Team Approach at the Medical Center of Delaware
Rita S. Meek, M.D. iii 169
Open Heart Surgery for Congenital Heart Defects: Overview and Review of the Early Experience at the Medical Center of Delaware
Kathleen W. McNicholas, M.D.
Jorge Serra, M.D.
N. Peter Karmilowicz, M.D.
Paschal M. Spagna, M.D.
Gerald M. Lemole, M.D. vii 413
Otitis Media: An Overview of Current Treatment
Robert L. Witt, M.D. ii 69
Overcoming Breast Cancer
Tammi D. Davis, M.D. (BR) x 614
Overview of Current Treatment, An, Otitis Media:
Robert L. Witt, M.D. ii 69

-P-

Pediatric Intensive Care (E)
Michael E. Norman, M.D. iii 188
Pediatric Nursing: Lessening the Emotional Trauma (E)
Jacqueline W. Levett, R.N., M.S.N. iii 196
Pediatric Oncology: The Team Approach at the Medical Center of Delaware
Rita S. Meek, M.D. iii 169
Pediatrics Special Issue
It's Everybody's Job (PP) iii 141
WVMI PRO and Delaware Physicians, The (SR)
William H. Duncan, M.D. iii 145
Feeding the Low Birth Weight Infant
Mary Lavelle Spear, B.S.N.
Michael L. Spear, M.D. iii 151

Multidisciplinary Approach to Development Delay in High Risk Infants, A
Nidia de Yanez, M.D. iii 159
Management of Closed Head Injuries in Children
Michael Alexander, M.D. iii 165
Pediatric Oncology: The Team Approach at the Medical Center of Delaware
Rita S. Meek, M.D. iii 169
Medical Ethics iii 181
Spotlight on the Guest Editor (E) iii 185
Evolution of Pediatrics in Delaware, The (E)
Michael L. Spear, M.D. iii 185
Role of Subspecialists in a Community Practice Setting, The (E)
Robert A. Doughty, M.D., Ph.D. iii 186
Pediatric Intensive Care (E)
Michael E. Norman, M.D. iii 188
Handicapped Children: There is Progress! (E)
Ted E. Chronister, M.D. iii 190
You've Come a Long Way, Pediatrics (E)
Maurice Liebesman, M.D. iii 195
Pediatric Nursing: Lessening the Emotional Trauma (E)
Jacqueline W. Levett, R.N., M.S.N. iii 196
Cheers for Dr. Spear (E)
Bernadine Z. Paulshock, M.D. iii 198
Delegate's Report: 1987 Interim Meeting of the AMA House of Delegates
Daniel A. Alvarez, M.D. iii 201
Cover
Douglas Bugel
Pendulum's Arc: A Lesson for Today's Physician, The (E)
Edward R. Sobel, D.O. iv 247
Physician examining infant. (BW) x 609
Physicians Observed (BR)
Carl T. Opderbeck, M.D. ii 127
Pitfalls of Peer Review, The (PP) iv 217
Plague Politics (E)
William J. Wiggin, Esq. Aviii 41
Pocket Atlas of MRI Body Anatomy (BR)
Bernadine Z. Paulshock, M.D. vii 459
Posttransfusion Hepatitis (E)
Jane Straughn, M.D. x 585
Practicing Physician's Approach to Headache, 4th ed (BR)
Lawrence J. Markman, M.D. iv 263
Principles and Applications, Cardiac Doppler Echocardiography
Christopher H. Wendel, M.D. v 285
Prescribing Habits of Delaware's Physicians, The (E)
Bernadine Z. Paulshock, M.D. ii 84
President's Page
Are We a Self-Serving Group? i 7
Dover or Bust ii 67
It's Everybody's Job iii 141
Pitfalls of Peer Review iv 217
Arbitration--A Rational Alternative? v 279
Protected Peer Review vi 349
"Tails" vii 411
Collaboration with *Delaware Lawyer* Aviii 5
Rx--Physician Political Involvement ix 411
Ronald McDonald House for Delaware, A x 551
Report of the President xi 627
Salve Atque Vale xii 697
Primary Care: New Patterns of Training (E)
David Platt, M.D. vii 443
Proceedings of the House of Delegates, 1987: Part I Medical Society of Delaware i 39
Proceedings of the House of Delegates, 1987: Part II Medical Society of Delaware ii 93
Proposal Whose Time Has Come, Special Report: Doctor-Patient Arbitration, A
Francis S. Babiarz
Phillip B. Bartoshesky
Victor F. Battaglia
Jeffrey S. Martin
Wayne A. Marvel
Roger Sanders
Mary Pat Trostle v 301
Protected Peer Review (PP) vi 349
Protestant's View of Organ Donation, A, John 15:13:
Marlene Walters, Ph.D. ix 513
Psychiatric and Psychological Aspects of AIDS
David E. Raskin, M.D. Aviii 38
Psychiatric Practice, Negligence in (E)
V. Terrell Davis, M.D. ii 81
Psychiatry and the Elderly: Diagnosis, Treatment, and Medical/Ethical Dilemmas
David E. Raskin, M.D. vi 371

Psychological Services
Jill Linden, Ph.D
Dorilyn English, Ph.D. xii 711
Public Health Issues in Delaware
Salve Atque Vale (P) xii 697
The Editor's Farewell
Bernadine Z. Paulshock, M.D. xii 701
The New Editor's Introduction
E. Wayne Martz, M.D. xii 702
The Division of Public Health
Lyman J. Olsen, M.D., M.P.H. xii 705
The Delaware State Tumor Registry
Allan Topham xii 707
"In Touch" Telephone Message System for Teenagers
Lucille P. Siegal, M.P.H.
Todd Krieble, M.P.H. xii 708
Public Health Nutrition
Anita M. Muir, M.S., R.D.
Elizabeth Fearnow, M.Ed., M.P.H., R.D. xii 709
Delaware's Bureau of Environmental Health
Lawrence J. Krone, Ph.D., M.P.H. xii 713
Regulating Health Care
James Harvey, M.P.H. xii 714
The Public Health Nurse
Barbara DeBastiani, RN.C., B.S.
Susan Shank, RN.C., B.S. xii 715
Computerized Health Risk Appraisal

Fred N. Breukelman xii 717
Genetics Services in Delaware
Louis E. Bartoshesky, M.D., M.P.H. xii 718
New Laws and Their Importance to Disease Prevention
Paul R. Silverman, Dr.P.H.
David E. Wolfe, P.A., R.N., M.P.H. xii 721
New Birth and Death Certificates
Michael L. Richards xii 726
Delaware Statewide Adolescent Health Study 1987
Lucille P. Siegel, M.P.H. xii 727
Smoking in Delaware: Economic Costs and Deaths Attributable to Cigarette Smoking in the State, 1985
Fred N. Breukelman
Paul S. Zeitz, D.O.
Thomas E. Novotny, M.D. xii 735
From the Obvious to the Optional (E)
E. Wayne Martz, M.D. xii 741
The Importance of Public Health Issues (E)
E. Wayne Martz, M.D. xii 741
Public Health for Public Good (E)
Lyman J. Olsen, M.D., M.P.H. xii 743
Spotlight on the Guest Editor (E) xii 43
Committee on Ethics (ME)
Robert W. Frelick, M.D. xii 747
Public Health Nurse, The
Barbara DeBastiani, RN.C., B.S.
Susan Shank, RN.C., B.S. xii 715
Public Health Nutrition
Anita M. Muir, M.S., R.D.
Elizabeth Fearnow, M.Ed., M.P.H. xii 709

-Q-

Quandaries in Reproductive Technology (E)
Jeffry I. Komins, M.D. ix 530

-R-

Renal Function and Disease in the Elderly
Laurence H. Beck, M.D. vi 363
Recurrent Perianal Streptococcal Cellulitis
Ricardo Castro, M.D.
Jaime Rivera, M.D. vii 421
Rediscovered Discipline, Medical Ethics: (E)
Maurice Liebesman, M.D. ix 475
Regulating Health Care
James Harvey, M.P.H. xii 714
Religious Perspectives
Catholic Perspective on Religion and Organ Transplantation, A
Thomas R. Ulshafer, S.S., Ph.D. ix 505
Choose Life: Jewish Tradition and Organ Transplantation
Kenneth S. Cohen ix 509
John 15:13: A Protestant's View of Organ Donation
Marlene Walters, Ph.D. ix 513
Remarks
Governor Michael N. Castle Aviii 16
Researcher's Initiative, The
Robert R. Redfield, M.D. Aviii 16
Rheumatic Diseases, Aerobic Exercise in the Management of
Russell J. Laborwitz, M.D.
Jayne Challman, M.S.
Scott Palmeri, R.P.T xi 659
Rheumatoid Arthritis, Advances in the Drug Management of
John H. Klippel, M.D.
Jeffrey Shiroky, M.D. xii 633
Rheumatology Special Issue
Report of the President (PP) xi 627
Advances in the Drug Management of Rheumatic Arthritis
John H. Klippel, M.D.
Jeffery Shiroky, M.D. xi 633
Growing Pains
Robert A. Doughty, M.D., Ph.D. xi 641
The Wolf Inside
John Stone, M.D. xi 647
Lyme Disease: A Historical Perspective
James H. Newman, M.D. xi 651
Aerobic Exercise in the Management of Rheumatic Diseases
Russell J. Labowitz, M.D.
Jayne Challman, M.S.
Scott Palmeri, R.P.T. xi 659
From Computer Modeling to FDA Approval: Research Strategy for the Discovery of New Anti-Arthritic Drugs
Neil R. Ackerman, Ph.D. xi 665
Comman Arthritic Manifestations (VB)
Richard Wallace, M.D.
Paul McCready, M.D. xi 669
Informed Consent (ME)
Robert W. Frelick, M.D. xi 675
Spotlight on the Guest Editor (E) xi 679
Introduction (D)
James H. Newman, M.D. xi 679
Omega-3 Fatty Acids in Rheumatoid Arthritis (E)
Joel M. Kremer, M.D. xi 679
A History of the Arthritis Foundation, Delaware Chapter (E)
Christopher R. Donoho, Jr., M.D. xi 681
Digitorum Nodi: Little Hard Knobs (E)
Bernadine Z. Paulshock, M.D. xi 683
Mental Illness Awareness (L)
Robert N. Dumin, M.D. xi 685
Rhythm Quizlets - Self Assessment
James M. Hofford, M.D. (BR) x 615
Role of Subspecialists in a Community Practice Setting, The (E)
Robert A. Doughty, M.D., Ph.D. iii 186
Ronald McDonald House for Delaware, A (PP) x 551
Rx--Physician Political Involvement (PP) ix 411

-S-

Saving Our Ozone Layer: The DuPont Company's Decision (E)
Bernadine Z. Paulshock, M.D. ix 533
Scanning electron micrograph of fescue (lawn

grass) pollen x 3000 (BW) iv 253
Sectional Human Anatomy (BR)
Joseph M. Ullman, M.D. iv 265
Should Pharmaceutical Companies Provide CME? (E)
Bernadine Z. Paulshock, M.D. x 592
Sjogren's Syndrome (BR)
James H. Newman, M.D. iv 262
Smoking in Delaware: Economic Costs and Deaths Attributable to Cigarette Smoking in the State, 1985
Fred N. Breukelman
Paul S. Zeitz, D.O.
Thomas E. Novotny, M.D. xii 735
Soft Tissue Rheumatic Pain: Recognition, Management, Prevention (BR)
James H. Newman, M.D. ii 128
Special Report: The State of Peer Review in Delaware Today
Victor F. Battaglia, Esq. iv 231
Special Report: Doctor-Patient Arbitration: A Proposal Whose Time Has Come
Francis S. Babiarz
Phillip B. Bartoshesky
Victor F. Battaglia
Jeffrey S. Martin
Wayne A. Marvel
Roger Sanders
Mary Pat Trostle v 301
Special Report: House Concurrent Resolution No. 121 vii 431
Spontaneous Pneumothorax, Current Management of
Festus B. Dada, M.D.
Allen L. Davies, M.D. i 17
Spotlight on the Guest Editor (E) iii 185
Spotlight on the Guest Editor (E) xii 743
State of Peer Review in Delaware Today, The (SR)
Victor F. Battaglia, Esq. iv 231
State of the Art, The (E)
Alvan R. Feinstein, M.D. vi 394
Statement on Physician Advertising (ME) vii 433
Stories of Sickness (BR)
David Platt, M.D. vii 461
Substitution of Surgeon Without Patient's Consent (8.13) (ME) i 11
Systemic Lupus Erythematosus
James H. Newman, M.D. (BR) x 613

-T-

"Tails" (PP) vii 411
Taking Care of the Well Elderly (E)
Herbert J. Keating, III, M.D. vi 389
Taking the Malpractice Crisis into Physician Hands (L)
Stephen R. Permut, M.D. x 605
Team Approach at the Medical Center of Delaware, Pediatric Oncology:
Rita S. Meek, M.D. iii 169
Teenagerss "In Touch" Telephone Message System for
Lucille P. Siegal, M.P.H.
Todd Krieble, M.P.H. xii 708
Textbook of General Medicine and Primary Care (BR)
David Platt, M.D. ii 129
Therapeutic Approach Based on 115 Consecutive Cases, Thoracic Outlet Syndrome:
Allen L. Davies, M.D.
William Messerschmidt, M.D. v 307
Therapy of Peptic Ulcer Disease: The Doctor's Dilemma (E)
Harris R. Clearfield, M.D. vii 443
Thoracic Outlet Syndrome: A Therapeutic Approach Based on 115 Consecutive Cases
Allen L. Davies, M.D.
William Messerschmidt, M.D. v 307
Thyroid Disorders in the Elderly
William L. Jaffee, M.D. vi 371

-V-

View Box
Intermittent Torticollis
Leslie E. Grissom, M.D. iv 241
Common Arthritic Manifestations
Richard Wallace, M.D.
Paul McCready, M.D. xi 669
View of Lock Hospital, Hyde Park Corner, London (BW) i 35
Venous Reconstruction in Venous Insufficiency Syndrome
Syde A. Taheri, M.D. vii 425

-W-

Where They Stand: Bush and Dukakis on Health and Related Topics vii 447
Wilmington Hospital's Obstetrical Clinic, Acceptance of Maternal Alpha-Fetoprotein Screening in
Karen Byrne-Essif, M.S.
John Naber, M.S.
Garrett H.C. Colmorgen, M.D. x 569
Wolf Inside, The
John Stone, M.D. xi 647

Women Doctors from Johns Hopkins
Jo Ann Rosenfeld, M.D. ii 73
WVMI PRO and Delaware Physicians, The (SR)
William H. Duncan, M.D. iii 145

-Y-

You've Come a Long Way, Pediatrics (E)
Maurice Liebesman, M.D. iii 195

Key:
(BR) Book Review
(BW) In Black and White
(E) Editorial
(L) Letter
(ME) Medical Ethics
(PP) President's Page
(VB) The View Box

DELAWARE MEDICAL JOURNAL INDEX
AUTHORS

NOTE: Because of the special nature of the August issue of the *Delaware Medical Journal* (a joint issue with the *Delaware Lawyer),* it is not included in the consecutive number system reflect throughout Volume 60. The index includes the following notation for the August issue: Aviii.

-A-

Aap, Dr.
Bioethical Humor ix 519
Ackerman, Neil R., Ph.D.
From Computer Modeling to FDA Approval: Research Strategy For the Discovery of New Anti-Arthritic Drugs xi 665
Alexander, Michael, M.D.
Management of Closed Head Injuries in Children iii 165
Alvarez, Daniel A., M.D.
Delegate's Report: 1987 Interim Meeting of the AMA House of Delegates iii 201
Delegate's Report: 1988 Annual Meeting of the AMA House of Delegates x 597

-B-

Babiarz, Francis S.
Doctor-Patient Arbitration: A Proposal Whose Time Has Come (SR)
(Phillip Bartoshesky)
(Victor E. Battaglia)
(Jeffrey S. Martin)
(Wayne A. Marvel)
(Roger Sanders)
(Mary Pat Trostle) v 301
Bartholomew, Michael J., Esq.
Flying Blind: The Insurance of Concealed Risks Aviii 62
Bartoshesky, Louis E., M.D., M.P.H.
Genetics Services in Delaware xii 718
Bartoshesky, Phillip
Doctor-Patient Arbitration: A Proposal Whose Time Has Come (SR)
(Francis S. Babiarz)
(Victor E. Battaglia)
(Jeffrey S. Martin)
(Wayne A. Marvel)
(Roger Sanders)
(Mary Pat Trostle) v 301
Battaglia, Victor, Esq.
State of Peer Review in Delaware Today, The (SR) iv 231
Doctor-Patient Arbitration: A Proposal Whose Time Has Come (SR)
(Francis S. Babiarz)
(Phillip Bartoshesky)
(Jeffrey S. Martin)
(Wayne A. Marvel)
(Roger Sanders)
(Mary Pat Trostle) v 301
Beck, Laurence J., M.D.
Renal Function and Disease in the Elderly vi 363
Breukelman, Fred N.
Computerized Health Risk Appraisal xii 717
Bryan, Everett D., M.D.
John A. Brown, Botanic Physician x 559
Bugel, Douglas
Cover, Pediatrics Special Issue iii
Byrne-Essif, Karen, M.S.
Acceptance of Maternal Alpha-Fetoprotein Screening in Wilmington Hospital's Obstetrical Clinic
(John Naber, M.S.)
(Garrett H.C. Colmorgen, M.D.) x 569

-C-

Cannon, Norman L., M.D.
The Changing Humors of Portsmouth, (BR) vii 462
Castle, Governor Michael N.
Remarks Aviii 4
Castro, Ricardo, M.D.
Recurrent Perianal Streptococcal Cellulitis
(Jaime Rivera, M.D.) vii 421
Challman, Jaque, M.S.
Aerobic Exercise in the Management of Rheumatic Diseases
(Russell J. Labowitz, M.D.)
(Scott Palmeri, R.P.T.) xi 659
Chronister, Ted E., M.D.
Handicapped Children: There is Progress! (E) iii 190
Cioffi, Gerald, D.D.S., M.S.
Early Detection: The Role of the Dentist Aviii 10
Clary, Cathryn, M.D.
Delaware Psychiatry Circa 1988 (E) x 587
Clayton, J. Wesley, III, M.D.
Breast Cancer: Diagnosis and Treatment (BR) vii 459
Clearfield, Harris R., M.D.
Therapy of Peptic Ulcer Disease: The Doctor's Dilemma (E) vii 443
Cohen, Kenneth S.
Choose Life: Jewish Tradition and Organ Transplantation ix 509

Colmorgen, Garrett H.C., M.D.
Acceptance of Maternal Alpha-Fetoprotein Screening in Wilmington Hospital's Obstetrical Clinic (Karen Byrne-Essif, M.S.) (John Naber, M.S.) x 569
Cosgrove, Martin J., M.D.
Are We a Self-Serving Group? (PP) i 7
Dover or Bust (PP) ii 67
It's Everybody's Job (PP) iii 141
Pitfalls of Peer Review, The (PP) iv 217
Arbitration--A Rational Alternative? (PP) v 279
Protected Peer Review (PP) vi 349
"Tails" (PP) vii 411
Collaboration with *Delaware Lawyer* (PP) Aviii 7
Rx--Physician Political Involvement (PP) ix 411
Ronald McDonald House for Delaware, A (PP) x 551
Report of the President (PP) xi 627

-D-

Dada, Festus B., M.D.
Current Management of Spontaneous Pneumothorax (Allen L. Davies, M.D.) i 17
Davies, Allen L., M.D.
Current Management of Spontaneous Pneumothorax (Festus B. Dada, M.D.) i 17
Thoracic Outlet Syndrome: A Therapeutic Approach Based on 115 Consecutive Cases (William Messerschmidt, M.D.) v 307
Davis, Tammi, M.D.
Overcoming Breast Cancer (BR) x 614
Davis, V. Terrell, M.D.
Negligence in Psychiatric Practice (E) ii 81
Day, Lorraine, M.D.
Informed Professional: Another View of HIV Testing, The Aviii 35
de Yanez, Nidia, M.D.
Multidisciplinary Approach to Development Delay in High Risk Infants, A iii 159
DeBastiani, RN.C., B.S.
The Public Health Nurse (Susan Shank, RN.C., B.S.) xii 715
Dickson-Witmer, Diana, M.D.
AIDS Hysteria in Delaware (E) ix 528
Minority Report of the AIDS Advisory Task Force Aviii 81
Dohono, Christopher R. Jr., M.D.
History of the Arthritis Foundation, Delaware Chapter, The (E) xi 681
Doughty, Robert A., M.D., Ph.D.
Role of Subspecialists in a Community Practice Setting, The (E) iii 186
Growing Pains xi 641
Dumin, Robert N., M.D.
Mental Illness Awareness (L) xi 685
Duncan, William H., M.D.
The WVMI PRO and Delaware Physicians, (SR) iii 145

-E-

English, Dorilyn, Ph.D.
Psychological Services (Jill Linden, Ph.D.) xii 711

-F-

Fearnow, Elizabeth, M.Ed., M.P.H., R.D.
Public Health Nutrition (Anita M. Muir, M.S., R.D.) xii 709
Feinstein, Alvan R., M.D.
The State of the Art, (E) vi 394
Fong, Gloria C., M.D.
Control of Communicable Diseases in Man, 14th Ed (BR) vii 464
Frelick, Robert W., M.D.
Informed Consent: An Ethics Question? (E) ix 523
Informed Consent (ME) xi 675
Committee on Ethics (ME) xii 747
Furrow, Barry Ray, Esq.
AIDS: Designing a Balanced Legislative Response Aviii 51

-G-

Glassman, Carl I., M.D.
Is Courtesy Old Hat? (E) v 321
Gostin, Lawrence, Esq.
AIDS as an Occupational Disease: Whose Right to Know? ix 479
Green, Leon Morton, M.D.
Isn't Something Missing? (L) iv 255
Grissom, Leslie E., M.D.
Intermittent Torticollis (VB) iv 241

-H-

Hall, William T., M.D.
Dr. Albert Ottow: Masterful Inactivity and Dying with Dignity (L) iv 257
Harvey, James, M.P.H.
Regulating Health Care xii 714
Hofford, James M., M.D.
Rhythm Quizlets - Self Assessment (BR) x 615

-J-

Jaffee, William L., M.D.
Thyroid Disorders in the Elderly vi 375

-K-

Keating, Herbert J. III, M.D.
Medical Grand Rounds: Old People and Surgery vi 351
Introduction: The Newest Specialty (E) vi 389
Taking Care of the Well Elderly (E) vi 389
Klippel, John H., M.D.
Advances in the Drug Management of Rheumatoid Arthritis (Jeffery Shicky, M.D.) xi 633
Komins, Jeffry I., M.D.

Quandaries in Reproductive Technology (E) ix 530
Kremer, Joel M., M.D.
Omega-3 Fatty Acids in Rheumatoid Arthritis (E) xi 679
Krieble, Todd, M.P.H.
"In Touch" Telephone Message System for Teenagers (Lucille P. Siegal, M.P.H.) xii 727
Krone, Lawrence J., Ph.D., M.P.H.
Delaware's Bureau of Environmental Health xii 713

-L-

Labowitz, Russell J., M.D.
Aerobic Exercise in the Management of Rheumatic Diseases (Jayne Challman, M.S.) (Scott Palmeri, R.P.T.) xi 659
Levinsky, Walter J., M.D.
Lung Cancer in Rubber Manufacturing Workers: Two Case Reports (Rosemary K. Sokas, M.D.) (Throne Sparkman, Jr., M.D.) x 573
Levinson, John M., M.D.
The Dilemma of the Nursing Shortage, iv 223
Levett, Jacqueline W., R.N., M.S.N.
Pediatric Nursing: Lessening the Emotional Trauma (E) iii 196
Liebesman, Maurice, M.D.
You've Come a Long Way, Pediatrics (E) iii 195
On the Diagnosis and Prevention of Bilateral Gluteal Hypermalacia Atrophicans Syndrome (Or Gallup Poll Disease) (E) iv 250
Medical Ethics: A Rediscovered Discipline (E) ix 475
Linden, Jill, Ph.D.
Psychological Services (Dorilyn English, Ph.D.) xii 711
Lyons, David J., Esq.
The Department of Justice: Dealing with a Constellation of Problems, Aviii 71
Legislative Posture, The Aviii 79

-M-

Maguire, John F.
A Commitment to Hope, Aviii 46
Markman, Lawrence J., M.D.
Practicing Physician's Approach to Headache, 4th ed (BR) iv 263
Marsili, Mark A., Ph.D.
Annual Review of Immunology, Vol. 5 (BR) iv 261
Martin, Jeffrey S.
Doctor-Patient Arbitration: A Proposal Whose Time Has Come (SR) (Francis S. Babiarz) (Phillip Bartoshesky) (Victor F. Battaglia) (Wayne A. Marvel) (Roger Sanders) (Mary Pat Trostle) v 301
Martz, E. Wayne, M.D.
The New Editor's Introduction, xii 702
From the Obvious to the Optional (E) xii 741
The Importance of Public Health Measures (E) xii 741
Marvel, Wayne A.
Doctor-Patient Arbitration: A Proposal Whose Time Has Come (SR) (Francis S. Babiarz) (Phillip Bartoshesky) (Victor F. Battaglia) (Jeffrey S. Martin) (Roger Sanders) (Mary Pat Trostle) v 301
McCready, Paul, M.D.
Common Arthritic Manifestations (VB) (Richard Wallace, M.D.) xi 669
Medical Society of Delaware
Proceedings of the House of Delegates, 1987: Part I i 39
Proceedings of the House of Delegates, 1987: Part II ii 93
Committees of the Medical Society of Delaware 1988 xii 749
Meek, Rita S., M.D.
Pediatric Oncology: The Team Approach at The Medical Center of Delaware iii 169
Messerschmidt, William, M.D.
Thoracic Outlet Syndrome: A Therapeutic Approach Based on 115 Consecutive Cases (Allen L. Davies, M.D.) v 307
Muir, Anita M., M.S., R.D.
Public Health Nutrition (Elizabeth Fearnow, M.Ed., M.P.H., R.D.) xii

-N-

Naber, John, M.S.
Acceptance of Maternal Alpha-Fetoprotein Screening in Wilmington Hospital's Obstetrical Clinic (Karen Byrne-Essif, M.S.) (Garrett H.C. Colmorgen, M.D., M.S.) x 569
Newman, James H., M.D.
Soft Tissue Rheumatic Pain: Recognition, Management, Prevention (BR) ii 128
Dubois' Lupus Erythematosus (BR) iv 261
Sjogren's Syndrome (BR) iv 262
Systemic Lupus Erythmatosus (BR) x 613
Clinical Concepts in Regional Musculoskeletal Illness (BR) x 613
Lyme Disease: A Historical Perspective xi 651
Introduction (E) xi 679
Norman, Michael E., M.D.
Pediatric Intensive Care (E) iii 188
Noseworthy, John, M.D.
Ethical Considerations in Solid Organ Transplants ix 497

Novotny, Thomas E., M.D.
Smoking in Delaware: Economic Casts and Deaths Attributable to Cigarette Smoking in the State, 1985.
(Fred P. Breukelman)
(Paul S. Zeitz, D.O.) xii 733

-O-

Olsen, Lyman J., M.D., M.P.H.
The Division of Public Health xii 705
Public Health for Public Good (E) xii 743
Opderbeck, Carl T., M.D.
Physicians Observed (BR) ii 127

-P-

Palmeri, Scott, R.P.T.
Aerobic Exercise in the Management of Rheumatic Diseases
(Russell J. Labowitz, M.D.)
(Jayne Challman, M.S.) xi 659
Paulshock, Bernadine Z., M.D.
The Death of Benjamin Rush, (E) i 32
The Prescribing Habits of Delaware's Physicians (E) ii 84
Cheers for Dr. Spear (E) iii 198
Integrating the Delaware Hospital: Does Anyone Remember? (E) iv 248
Common Diagnostic Tests: The Book and the Problem (E) v 232
The Gray Boomers, (E) vi 393
Pocket Atlas of MRI Body Anatomy (BR) vii 459
Saving Our Ozone Layer: The DuPont Company's Decision (E) ix 533
Amplification (E) x 587
Should Pharmaceutical Companies Provide CME? (E) x 592
Digitorum Nodi: Little Hard Knobs (E) xi 683
The Editor's Farewell xii 701
Pellegrino, Edmund D., M.D.
Is Medical Ethics a Tradition and Ideal Without a Future? (ME) vi 385
Perkel, Robert L., M.D.
Medical Ethics in Medical Practice ix 491
Permut, Steven J., M.D.
Taking the Malpractice Crisis Into Physician Hands (L) x 605
Platt, David, M.D.
Memoire sur la Fermentation Applee Lactique (Medical Classics) i 23
Textbook of General Medicine and Primary Care (BR) ii 129
Primary Care: New Patterns of Training (E) vii 443
Nelson's Textbook of Pediatrics (BR) vii 460
Stories of Sickness (BR) vii 461
Medical Need and the Private Practice Physician (E) ix 532
Hematology: The Blossoming of a Science (BR) x 612

-R-

Raskin, David E., M.D.
Medical Legal Case Conference: The Doctrine of Informed Consent v 313
Psychiatry and the Elderly: Diagnosis, Treatment, and Medical/Ethical Dilemmas vi 371
Psychiatric and Psychological Aspects of AIDS Aviii 38
Redfield, Robert R., M.D.
The Researcher's Initiative, Aviii 16
Richards, Michael L.
New Birth and Death Certificates xii 726
Rivera, Jaime, M.D.
Recurrent Perianal Streptococcal Cellulitis
(Ricardo Castro, M.D.) vii 421
Rosenfeld, Jo Ann, M.D.
Women Doctors from Johns Hopkins ii 73
Disease and Discovery (BR) vii 461
Roth, William V., Jr.
Health Care of the Elderly: Infinite Promise in a World of Limited Resources vi 379

-S-

Sanders, Roger
Doctor-Patient Arbitration: A Proposal Whose Time Has Come (SR)
(Francis S. Babiarz)
(Phillip Bartoshesky)
(Victor F. Battaglia)
(Jeffrey S. Martin)
(Wayne A. Marvel)
(Mary Pat Trostle) v 301
Sayers, Daniel G., M.D.
The "Crack" in the Emergency Door (E) v 325
Schweizer, Edward, M.D.
Delaware Psychiatry Circa 1988
(Cathryn Clary, M.D.) (E) x 587
Shank, Susan, RN.C
The Public Health Nurse
(Barbara DeBastiani, RN.C., B.S.) xii 715
Shellenberger, William D., M.D.
Industrial Medicine and Community Doctors (E) i 30
Shiroky, Jeffery, M.D.
Advances in the Drug Management of Rheumatoid Arthritis
(John H. Klippel, M.D.) xi 633
Siegel, Lucille P., M.P.H.
Delaware Is in Touch (L) iv 255
"In Touch" Telephone Message for Teenagers
(Todd Krieble, M.P.H.) xii 708
Delaware Statewide Adolescent Health Study-1987 xii 727
Silber, Tomas J., M.D., M.A.S.S.
Abortion in Adolescence: A Clinician's Reflections ix 487
Silverman, Paul R., Dr., P.H.

Silverman, Paul R., D.P.H.
New Laws and Their Importance to Disease Prevention
(David E. Wolfe, P.A., R.N., M.P.H.) xii 721
Silverstein, H. Robert, M.D.
Allowing the Dying to Die (ME) x 579
Sobel, Edward R., D.O.
The Pendulum's Arc: A Lesson for Today's Physician, (E) iv 247
Long Term Care: What Does It Cost? (E) x 591
Sokas, Rosemary K., M.D.
Lung Cancer in Rubber Manufacturing Workers: Two Case Reports
(Thorne Sparkman, Jr., M.D.)
(Walter J. Levinsky, M.D.) x 573
Spagna, Paschal M., M.D.
Open Heart Surgery for Congenital Heart Defects: Overview and Review of the Early Experience at the Medical Center of Delaware
(Kathleen W. McNicholas, M.D.)
(Jorge Serra, M.D.)
(N. Peter Karmilowicz, M.D.)
(Gerald M. Lemole, M.D.) vii 413
Sparkman, Throne Jr., M.D.
Lung Cancer in Rubber Manufacturing Workers: Two Case Reports
(Rosemary K. Sokas, M.D.)
(Walter J. Levinsky, M.D.) x 573
Spear, Mary Lavelle, B.S.N.
Feeding the Low Birth Weight Infant
(Michael L. Spear, M.D.) iii 151
Spear, Michael L., M.D.
Feeding the Low Birth Weight Infant (Mary Lavelle Spear, B.S.N.) iii 151
Evolution of Pediatrics in Delaware (E) iii 185
Stillabower, Michael F., M.D.
National Cholesterol Education Program (E) i 29
Stone, John, M.D.
The Wolf Inside xi 647
Straughn, Jane, M.D.
Posttransfusion Hepatitis (E) x 585

-T-

Taheri, Syde A., M.D.
Venous Reconstruction in Venous Insufficiency Syndrome vii 425
Tolpin, Eugene I., M.D.
Cardiovascular Anesthesia (BR) vii 460
Topham, Allan
The Delaware State Tumor Registry xii 707
Trostle, Mary Pat
Doctor-Patient Arbitration: A Proposal Whose Time Has Come (SR)
(Francis S. Babiarz)
(Phillip Bartoshesky)
(Victor F. Battaglia)
(Jeffrey S. Martin)
(Wayne A. Marvel)
(Roger Sanders) v 301

-U-

Ullman, Joseph M., M.D.
Sectional Human Anatomy (BR) iv 264
Ulshafer, Thomas R., S.S., Ph.D.
A Catholic Perspective on Religion and Organ Transplantation ix 505

-V-

Vates, Thomas S. Jr., M.D.
Care of the Brain Dead and Other Troubling Patients (E) ix 529

-W-

Wallace, Richard, M.D.
Common Arthritic Manifestations (VB) xi 669
Walters, Marlene, Ph.D.
John 15:13: A Protestant's View of Organ Donation ix 513
Wendel, Christopher H., M.D.
Cardiac Doppler Echocardiography Principles and Practices v 285
Wendel, Henri F., M.D.
Salve Atque Vale (PP) xii 697
White, Barry E., M.D.
Diagnosis of Thoracic Outlet Syndrome (L) x 606
Wiggin, William E., Esq.
Plague Politics (E) Aviii 41
Willard, Brian M.
Clinimetrics (BR) x 611
Witt, Robert L., M.D.
Otitis Media: An Overview of Current Treatment ii 69
Wolfe, David E., P.A., R.N., M.P.H.
New Laws and Their Importance to Disease Prevention.
(Paul R. Silverman, Dr. P.H.) xii 721

-Y-

Yanez, Nidia de, M.D.
see de Yanez, Nidia, M.D.

-Z-

Zeitz, Paul S., D.O.
Smoking in Delaware: Economic Costs and Deaths Attributable to Cigarette Smoking in the State, 1985.
(Fred N. Breukelman)
(Thomas E. Novotny, M.D.) xii 735

KEY:
(BR) Book Review
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(ME) Medical Ethics
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(VB) The View Box

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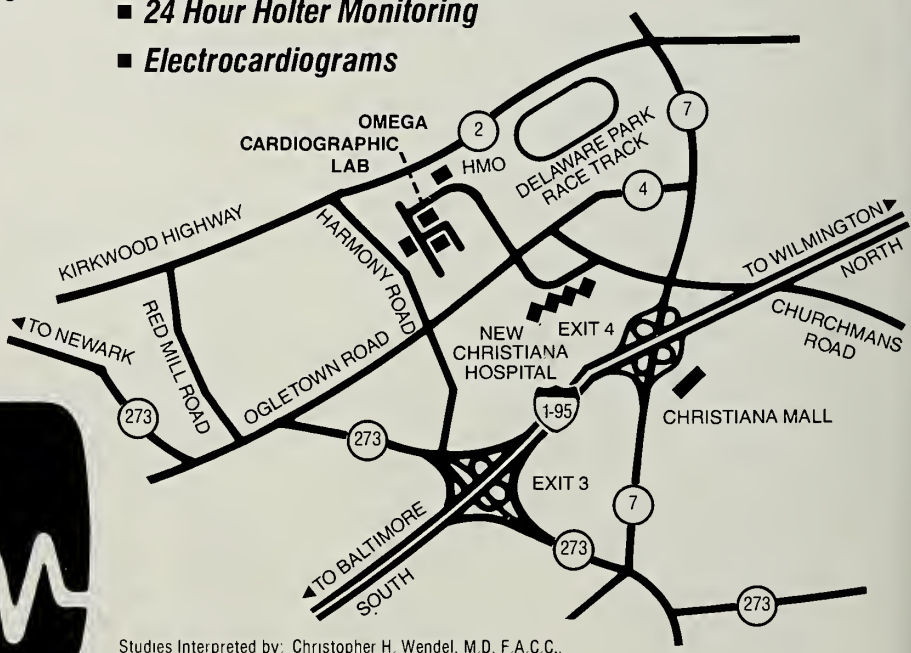

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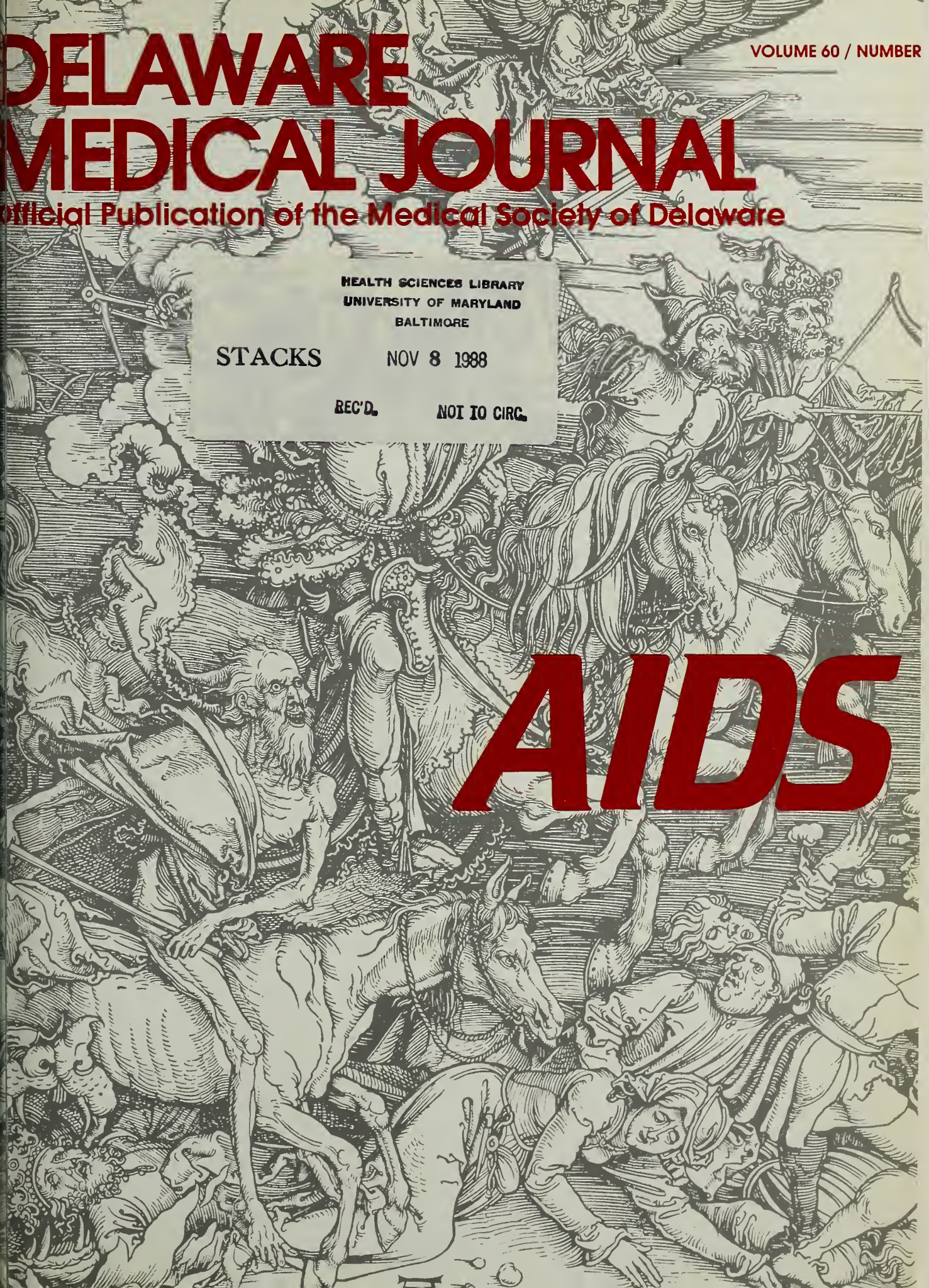

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CONTENTS

4 Remarks by Governor Michael N. Castle

5 EDITOR'S PAGE

10 Early Detection: The Role of the Dentist. . . . *Dr. Gerald Cioffi*

16 The Researcher's Initiative . . . . *Robert R. Redfield*

27 Considerations and Potential Pitfalls in Lab Tests for AIDS. . . . *Cyril H. Wecht*

35 The Informed Professional: Another View of HIV Testing . . . . *An Interview with Dr. Lorraine Day*

38 Psychiatric and Psychological Aspects of AIDS. . . . *David E. Raskin, M.D.*

41 Plague Politics . . . . *William E. Wiggin*

43 Informed Consent and Confidentiality Regarding HIV Related Tests

46 A Commitment to Hope Intellect, Capital, and Social Responsibility . . . . *John F. Maguire*

51 AIDS: Designing a Balanced Legislative Response . . . . *Barry Ray Furrow*

62 Flying Blind: The Insurance of Concealed Risks. . . . *Michael J. Bartholomew*

71 The Department of Justice: Dealing with a Constellation of Problems. . . . *David J. Lyons*

79 The Legislative Posture. . . . *David J. Lyons*

81 Minority Report of the AIDS Advisory Task Force

Cover: *The Four Riders of the Apocalypse*, ca. 1497-98, Albrecht Durer 1471-1528. Courtesy of The Harvard University Art Museums (Fogg Art Museum). Gift of Paul J. Sachs.

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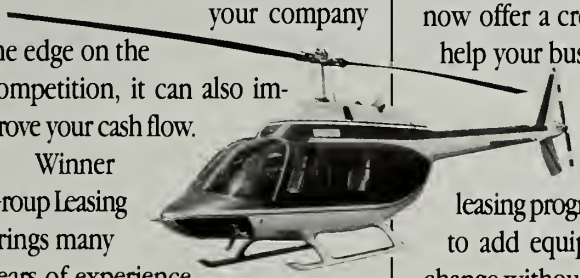

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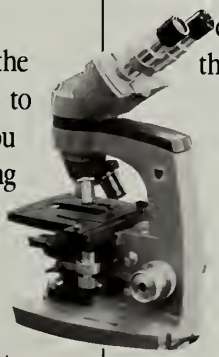

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Governor Michael N. Castle addressed a combined audience of legislators, health care professionals, social workers and members of the general public at the Professional Conference on AIDS on April 16, 1988.

Remarks by Governor Michael N. Castle

I am very pleased to have the opportunity to discuss this important issue with you today.

Let me begin by commending the Delaware State Bar Association, the Delaware Dental Society, and the Medical Society of Delaware for organizing this conference.

For the past several years, the state has been deeply involved and committed to addressing the serious issues posed by Acquired Immune Deficiency Syndrome, or AIDS.

As you will no doubt hear later today, agencies within the state government have been working to understand, to educate people about, and to combat this terrible killer.

On their behalf, welcome to the fight.

The professionals represented by this conference have the ability to make a great deal of difference in educating people and helping to stop the spread of AIDS in Delaware.

I hope that, as you educate yourselves about AIDS, you will discover ways to educate and help your clients and patients.

By doing so, we can at least treat and cure the plague of misinformation about AIDS.

As I said, the state has been involved in this effort for several years and I should like to take a few minutes to describe the record of what has been accomplished.

It is a good record, a strong record, and in some ways Delaware is far ahead of all but a handful of other states.

But first I want to define the issue of AIDS—from the state's perspective.

This is necessary because the public perception of AIDS has been evolving almost since it began to affect significant numbers of people in America.

Where once it seemed to affect only homosexuals and a small number of ethnic groups, today it affects homosexuals and heterosexuals alike; it affects women as well as men; no social or ethnic group is immune.

In fact, the single largest at-risk population today is not homosexuals, but illegal intravenous drug users.

It is also, to a considerable degree, a disease affecting prostitutes.

Having said that, let me make an important point: *Our attitude about the problem, our determination to solve it once and for all, must not be colored by any personal or social view of the groups involved.*

AIDS is a *medical* problem, and society and the state must view it as such.

But it is also a highly charged emotional issue. It is a disease that kills all its victims—sparing none. It is potentially as dangerous and destructive of life and society as any plague in the Middle Ages. It snuffs out young lives—tragically.

ABOUT THIS SPECIAL ISSUE

This is a first for two publications, a joint issue of *DELAWARE LAWYER* and *DELAWARE MEDICAL JOURNAL*. We find a symbolic fitness in a collaboration parallel to a professional alliance to confront the great health and social catastrophe of our time.

In late 1987 representatives of the Bar Association, the Dental Association, and the Medical Society convened to plan a Professional Conference on AIDS. On April 16 of this year an audience of 300 convened at the University of Delaware's Clayton Hall to hear the views of distinguished surgeons, dentists, lawyers, and scientists. The conference attracted far more than members of the three committed professions. Prominent legislators, health care workers, social workers, and highly articulate members of the general public came to learn and contribute to the cause of AIDS enlightenment. Much of the content of this issue is drawn from presentations made at the conference.

In July of this year The American College of Legal Medicine sponsored a brilliant two day AIDS symposium in Arlington, Virginia. It is our good fortune to publish some of the material presented there.

If there is a single message to be drawn from these endeavors it is this. The most important preventative against the spread of a plague for which there now exists no cure is education. We dedicate this joint issue to that proposition. *Fiat lux!*

Bill Wiggin and I recently attended a conference on AIDS sponsored by the American College of Legal Medicine. We were so impressed with the program that we persuaded the sponsors to allow us to publish one of the presentations in this issue.

There were two things I learned at the conference that impressed me greatly. The first was the response to a question I asked C. Everett Koop, the Surgeon General: Was there any "good news" with regards to AIDS? He replied that intense research into retroviruses would likely assist in the solution of other medical problems. I had hoped for something more, some encouragement about the spread of the disease. I thought he might say that heightened public awareness had resulted in a dramatic decrease in the rate of new cases, or that the incidence of IV drug abuse was declining. He didn't say what I'd hoped, because I don't think those things are happening. The educational messages, while important, are not necessarily reaching the people most at risk.

The second thing about the program that struck me was a discussion of AIDS dementia. It presents itself in cases where people are HIV positive and may not be aware of it. More important, they may not have any physical symptoms attributable to the disease. Consequently, the dementia is very difficult to foresee or to diagnose. It manifests itself in a gradual subtle deterioration of judgment. The implications are frightening. As a Superior Court Judge, I am concerned that undiagnosed AIDS dementia might be the root of a defendant's illegal conduct, or that it might affect a defendant's ability to participate in the presentation of a defense. In industry, employers have to concern themselves with those who occupy sensitive positions where the lives of others may be jeopardized by mistakes of judgment. The obvious examples are railroad conductors, pilots, and plant operators, to name but a few. AIDS dementia represents yet another complication in an already complex illness.

A recurring theme in this publication is the need to strike the difficult balance between the legitimate need to protect society and the need to protect our hard won and precious civil rights. In 1988 we are making amends to the Americans of Japanese descent who were wrongfully detained in concentration camps during World War II. Yet we hear suggestions that everybody be tested and that those who are HIV positive be shipped off for the good of the society. I don't believe any such suggestions will ever be seriously considered, but the fact that they are made warns us of the need to be vigilant in protecting the civil rights of each citizen at every step along the way, knowing, as we do, that the impact of the disease on our society will grow much greater in the decade ahead and knowing, too, that as the incidence increases along with the attendant costs, society's anger and frustration will increase.

(Continued on page 7)

Where once it seemed to affect only homosexuals and a small number of ethnic groups, today it affects homosexuals and heterosexuals alike; it affects women as well as men; no social or ethnic group is immune.

To date, AIDS has claimed 50 lives out of the estimated 120 known cases in Delaware, and we believe that 4,000 Delaware residents are infected with the virus. By 1991, it is predicted that the total number of AIDS victims here—including those who will have succumbed to the disease—will exceed 1,000 cases.

As we have learned that AIDS can strike anyone, and as our knowledge of the pathology of AIDS has grown—and with it our understanding that it is a changing, elusive killer—the potential for fear has grown. Thus those who convey information to the public about AIDS—whether they are in state government, in the private sector, or in the media—must exercise exceptional care. AIDS is a matter of great concern to people; and it is our job to educate them, not frighten them. Let me take a few minutes to tell you about the state's efforts. They are significant, and in a number of ways innovative.

AIDS Advisory Task Force

The AIDS Advisory Task Force was formed two years ago under the auspices of the state Division of Public Health. Membership in the task force represents virtually every group with an interest in the issue—the medical profession, the Gay and Lesbian Alliance, and state agencies.

Last September the task force issued its first report, recommending a number of steps at both the community and governmental levels.

The recommendations covered:

- Development of public policies.
- Education programs.
- Voluntary testing and counseling.
- And treatment of AIDS victims.

Because at least four cabinet-level departments must deal with various aspects of AIDS, it was proposed through the Human Services Cabinet Council, which has the responsibility for coordinating interagency programs, that

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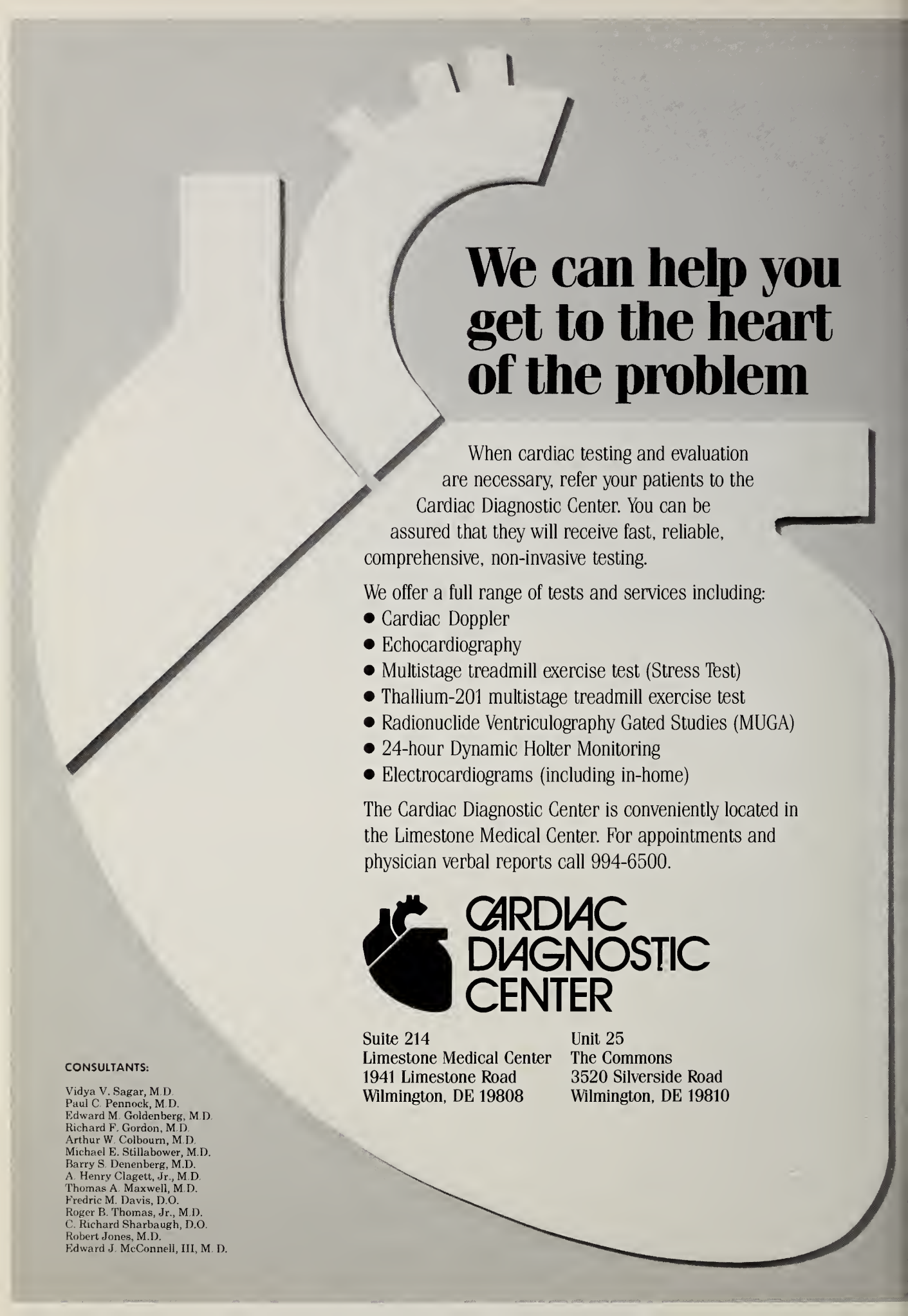

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Governor Castle's Remarks
(continued)

each department address those recommendations with policies specific to their own needs.

In addition, the Office of State Personnel was asked to develop general policies related to the state as an employer—including hiring policies and policies related to employee/client interactions.

The result is that today we have comprehensive policies and sound practices in place, with a strong emphasis on prevention and education.

Health and Social Services

Through the Division of Public Health, the Department of Health and Social Services has taken responsibility for developing and disseminating health policies about AIDS; for providing roughly 3,000 voluntary testing sessions a year—we are able to provide testing within a week of the request in New Castle County, within two weeks in Kent and Sussex counties; for providing public awareness and education programs for about 1,000 people a month; management of over 50 active AIDS cases per month; and coordination of all related AIDS activities.

That means fielding over 600 calls monthly and conducting roughly one meeting a day, five days a week with groups from throughout the community which are interested in learning more about AIDS.

In addition, the department's Division of Alcohol, Drug Abuse and Mental Health requires its contractors to provide clients with information about the AIDS risk factor associated with IV drug use. If we are going to stop the tragic spread of AIDS, we must make drug users understand the risk they are taking.

Public Instruction

The Department of Public Instruction has developed a model mandatory education curriculum and materials for kindergarten through twelfth grade—designed to give students important facts about AIDS and its prevention. We have developed guidelines for bus drivers and school personnel regarding the handling of body fluids. We have in place policies regarding the admission and attendance of students infected with AIDS.

(Continued on next page)

Susan C. Del Pesco

Martin J. Cosgrove

It was especially gratifying for the Bar Association to have had the opportunity to work with the Dental and Medical Societies of this State in presenting the AIDS conference last April. My most sincere thanks to the interprofessional committee which worked together to make the conference a reality.

I am confident that this publication, which embodies much of the meeting, will be valuable to all who take the time to read it.

Susan C. Del Pesco

This issue of *Delaware Medical Journal* departs from our usual format of learned articles addressed exclusively to the medical profession. It is a collaboration among doctors, dentists, and lawyers in which the expert knowledge and distinct viewpoints of three professions are brought to bear on a social problem that defies the abilities of any isolated group of experts to solve.

AIDS, of course, is first and foremost a medical problem, as Governor Castle wisely observes in his introductory remarks at page 4. The great advantage of the April 16 Conference, from which most of the articles in this issue were drawn, was the opportunity it gave topflight medical and dental experts like Doctors Day, Redfield, and Cioffi, to inform lawyers, legislators, and the intelligent lay public about the current state of scientific knowledge, without which the combined effort to control AIDS cannot succeed. I believe that it was no less informative for members of our profession to hear of the legal, economic, and social concerns that must go into any humane and effective equation for responding to this major threat to our well-being as individuals and as a nation. I am delighted to see the professions united in a common cause.

Martin J. Cosgrove, M.D.
President, Medical Society of Delaware

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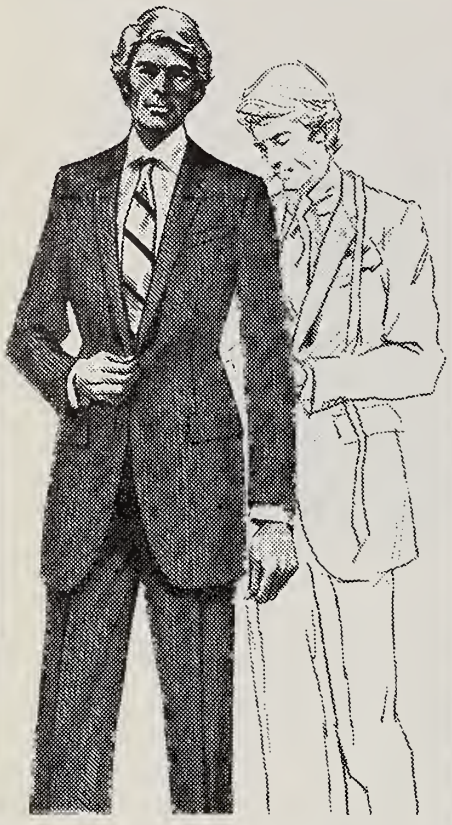

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Governor Castle's Remarks
(continued)

Services for Children, Youth and their Families

The Department of Services for Children, Youth and their Families has developed policies regarding the care of foster children who test positive to the AIDS virus. In addition, the Children's Bureau is under contract to recruit foster parents for children with serious health problems including AIDS, and the Bureau is developing a plan for identifying and then providing additional social services needed by children and families with AIDS.

Correction

AIDS is a serious problem in our nation's prisons, and the Department of Correction in Delaware has made once voluntary AIDS education classes madatory for inmates so that they understand how AIDS spreads through homosexual contacts and IV drug use. We have provided classes for all female prisoners and more than ten percent of male prisoners. We provide voluntary testing for inmates (currently 14 are known to be HIV positive). And we are developing an AIDS education program for correctional officers.

The Next Step

Since we believe that, for at least the next five years, the number of AIDS cases in Delaware will double annually, the state is already proceeding with the next steps to fight this disease.

In addition to almost $86,000 in state funds directed towards AIDS programs during the current fiscal year, we have received over $330,000 in federal funds for prevention efforts this year. The budget I have proposed would increase state funding; additionally, we are seeking—with a strong degree of optimism about our chances of success—double the current federal funding the next fiscal year. This new funding would allow us to add nine people to the ten already providing counseling and testing, education, and case tracking.

- We are already at work determining how the new AIDS cases will affect our ability to handle the caseload.
- And we are in the midst of planning alternative care systems for AIDS patients.

As you no doubt know, it has been proposed that a privately run care facility for AIDS patients be established on state property, and my first reaction to the proposal was positive.

- The Division of Mental Health is developing an estimate of the increased need for AIDS prevention and education programs made necessary as more drug users seek help.
- The Department of Public Instruction is conducting a follow-up survey to make sure that the AIDS education program is being fully implemented, and DPI is forming a crisis team which would go into action if a Delaware student is found to have AIDS.
- The Department of Correction is presently determining how an increased AIDS population will affect both the operation—and the cost of operation—of our prisons.

Obviously, the growing number of IV drug users with AIDS will affect our decisions about future programs. I am asking Secretary Eichlier to develop an estimate of new IV-drug-use-related cases, and to develop a comprehensive plan to deal with these cases.

As I said earlier, our knowledge of AIDS keeps changing, as does the profile of the disease and its victims. Given this state's limited role in dealing with AIDS (the states cannot be expected to undertake any sort of research projects), we must maintain our flexibility and keep finding new and more effective ways to make our education and prevention programs successful. The efforts of the state *must* be supplemented by efforts by groups like yours, by conferences like this one. Until recently, much of the responsibility for educating, testing, counseling and helping was borne by the Delaware Lesbian and Gay Health Advocates. They have done an exceptional job of promoting understanding and helping AIDS victims. Out of this conference, I hope, will come a commitment by Delaware legal and medical community to do the same thing. ■

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Early Detection: The Role of the Dentist

Dr. Gerald Cioffi

I should like to start from a clinical perspective and look at the word itself—AIDS. It's a good descriptive term. It's an acquired immune deficiency syndrome. Those are all very important points. How is it acquired? I think we're all now well aware that it is acquired by infection with the HIV virus. Immune deficiency is the hallmark of this illness. What separates it from other illnesses and syndromes is the severe immune deficiency that can be a part of this illness. The last word is very important as well: *syndrome.* The word tells us that we are not looking at a disease. AIDS is *not* a disease; it's an *illness* encompassing a great number of diseases. When we put particular combinations of diseases together in a single patient and couple that with the presence of the HIV virus we have fulfilled the definition of a patient with AIDS.

I began treating AIDS patients in the service expecting to see the lesion or the disease of AIDS, but I didn't find it. What I found instead was a multiplicity of diseases wrapped up in a package. And I think that's a very important point, often overlooked in our approach to this illness. AIDS is a combination of diseases and we have to look at patient management from that perspective.

Dr. Winslow mentioned during his remarks that many patients, once they acquire immune deficiency as a portion of this illness, succumb and become victims of multiple emergent secondary infections from organisms already present in their bodies. I want to discuss the role of the dentist in the treatment of this patient population.

One patient, a young man in his mid 20s, came to the dental clinic for treatment of a gum condition, a gingival condition. He had a particular condition that we call ANUG or acute necrotizing ulcerative gingivitis or periodontitis. It was very refractory to treatment despite all standard therapy. *He did not get well.* This was back in 1983.

We began to look for reasons why an otherwise normal, healthy person was not responding to a pathogen that all of us would usually handle very easily. The answer lay in immune deficiency. This particular case was my first clinical experience of making an original diagnosis from dental findings of HIV infection and immune deficiency. I have found since that time that it's been a very common experience in my practice. In fact, many of the earliest signs and symptoms of immune deficiency will occur in the oral cavity. And for a very good reason — the greatest microbiotic challenge to the human body is through the oral cavity. Since the earliest, most subtle changes in immune deficiency will occur in the oral cavity, I have found that the dental profession is in a very good position to make early diagnoses and original diagnoses of this infection. This has become a very common clinical experience. Now when we look at certain types of infection in an otherwise healthy individual not on other medications, we must entertain the possible diagnosis of immune deficiency. I find myself in daily practice in the position where it is not merely appropriate but obligatory that I be able to rule out immune deficiency. Accordingly, there will often be reason and need for the dentist to order an antibody screen for HIV infection.

Now many of the conditions I encounter are not uncommon to the family of patients who are immune deficient, because of radiation, immunotoxic drugs, chemotherapy for various neoplasias, genetic or developmental deficiency, or viral infection. The common latent manifestations of the herpes class of viruses is a good example. They are very common in the immune deficient patient. There is a dramatic similarity between all the classes of immune deficient patients and in particular within the class in the acquired immune deficiency syndrome. Unfortunately, once patients have begun to manifest immune deficiency there is very little that we can do for them at this time. They are very refractory to treatment for both their oral and their systemic manifestations and they require chronic therapy. We are getting better in supporting some of the concomitant diseases *because we're getting them sooner.* That is a very, very important point in the treatment of this illness. From my point of view as a clinician, I'd very much like to see testing — because I know that from a therapeutic standpoint if I don't get into the picture early in the game the patient is going to have a very difficult time with the management of his complications, which are predictable and unfortunately irreversible.

I was very glad to hear Governor Castle observe that this is a *medical* problem. In the late 70s and early 80s we treated it as every kind of problem but a medical one. It is a sexually transmittable blood borne viral infection. Any kind of policy or legislation that deals with this issue should begin with that recognition and focus. The role of the infectious disease department in the medical institutions is pivotal. This group of patients *belongs* with the infectious disease clinic, *belongs* with the infectious disease specialist. It's difficult to manage infectious diseases. I think that we're going to conquer many of the mistakes that we made early, many of the misconceptions, and many of the prejudices about this particular illness when we finally come to grips with it as an infectious disease, because that is what we're facing.

I'd like to make another important point. All the conditions and all the diseases we encounter in AIDS patients can be acquired in other ways, and other patient populations can manifest the same diseases. The point is that today you have to be diagnostically and clinically attuned to recognize what was not the case ten or fifteen years ago: Immune deficiency is now becoming one of the more common ways that patients acquire these diseases.

The herpes classes of virus are very important in this patient population, and indeed in all populations of immune depressed patients. We all have these viruses. They're mostly childhood diseases. We carry them latently and harmlessly for life because we have competent immune systems to hold them back. When those systems break down then we have recurrent infections. With immune depression we find that a normal cold sore, which many people have occasionally, produces an overly dramatic inappropriate response, which suggests and leads to immune depression. When I use barrier techniques with my immune depressed patients, it's for a different reason from what is commonly thought. I use barrier techniques and isolations to protect the *patient,* who is now immune deficient. Common microbiota in the practice and from my staff are now a very big threat to the patient.

For example during a normal routine dental examination office visit I treated a patient who had a very subtle pigmented, slightly discolored lesion on the roof of the mouth. "Mr. Jones, you've got a small pigmented area in the palate." Examination, biopsy, and testing lead to a diagnoses of HIV infection, intraoral Kaposi's scarcoma and a patient well into severe immune deficiency. Intraoral lesions are often the first constitutional clinically evident sign of the illness. For example, white hairy leukoplakia is becoming a very useful clinical marker for the progression of the illness. Patients who have white hairy leukoplakia as part of their syndrome have a much more rapid rate of development of the full blown AIDS syndrome. We must remember that the AIDS portion of the illness is the end of the spectrum. Patients with this particular intraoral manifestation predictably get sicker faster and have a much more rampant

(Continued on next page)

Gerald A. Cioffi, a Commander in the United States Navy Dental Corps, is a graduate of the University of Pennsylvania School of Dental Medicine. He also holds an M.S. degree in education from the School of Graduate Education of the same University. He is a consultant at the Naval Hospital in Jacksonville, Florida, where he heads the Department of Oral Medicine. Dr. Cioffi is also a well known speaker at continuing education programs. His remarks are drawn from his address to the Professional Conference on AIDS.

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Early Detection
(continued)

run of their illness than patients who do not have hairy leukoplakia. We now have a clinical marker that can be predictive of patient outcome. A colleague in the neighboring clinic called me and said that his patient had an unusual lesion on the side of his tongue. One look at this lesion of candidiasis from my clinical standpoint and I was very suspicious of immune deficiency. The HIV test was positive.

I have a difficult time understanding the arguments over testing. I first started seeing AIDS patients in 1983 at Bethesda Naval Hospital and have been seeing them regularly since that time. In that five years I have never had any difficulty or any refusal by a patient to take the test. I sometimes think that we sit on the side and make up ideas about this patient population without ever sitting down and talking to somebody who has the illness. The patients are very appreciative to receive treatment and very much concerned about their health. After consultation I've never had any problem or even any hesitation on the patient's part to get the appropriate workup. It has never been a problem.

Another point that I want to make is the importance of the association of the dental and medical teams. When we are doing dentistry on the medically compromised patient, the dentistry is medicine. When it comes to management of this patient population, if we begin divided we will end up together. These patients *must* have joint management. The course of the illness leads to multiple, unavoidable hospital admissions and chronic management. There is no one-time fix for these patients. And there has to be constant communication between the specialists and between the professions in the management of these patients. You will very shortly find yourselves being drawn together because you simply can't adequately manage the patient if you don't. So you can't begin by trying to divide the treatment team and then all of a sudden find yourself in a clinical situation where you must hurriedly go out and find a dentist who can work with the team. It has been our experience that you make out much better and the patient makes out tremendously better if you begin with the team approach. These patients need the attention of multiple specialists and you need to have these people together in one place with a protocol, a clinic, and a facility that knows how to get things done in a very timely manner. For me, that's a very practical approach and I'm sure I will be criticized for maybe not taking into consideration all the social and legal issues, but I have a bias toward treatment of the patient.

When we first got into this business we sat down and tried to decide how to best balance all the social factors, political factors, and medical factors, and then we drew up a set of rules. We began to learn almost immediately that the system we had set up crippled the hospital and we couldn't treat the patients. That began a process of rediscussion and reaccommodation. Now there is no such problem. We have gotten through the issue and I hope you will too, because it is absolutely inappropriate for a health care professional to treat a patient

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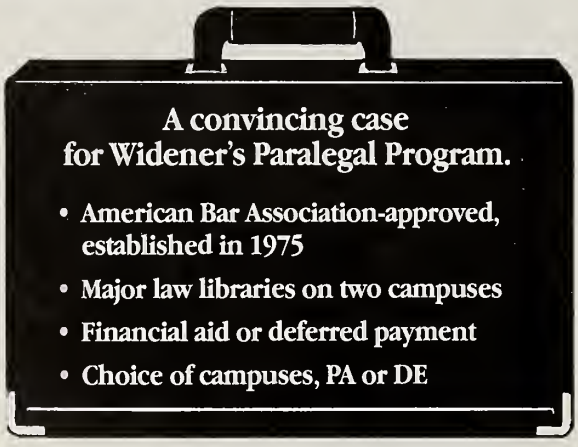

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without full access to his medical history. That's not in the patient's interest or the health care professional's. In the management of a multifaceted infectious disease you need to know the complete clinical picture. That was a stumbling block in the beginning and it led to inappropriate treatment. That is why we're now back to the point of doing for this particular patient population what we do with *all* our infectious disease patients. It *is* a medical problem.

There are some *truly* unique things about this. For example, once this patient population acquires their immune deficiency, *mortality is 100 percent.* Unfortunate but true at this time. They become part of the terminally ill population and as in the case of those suffering from inoperable tumors, incurable cancers, and other terminal illnesses, these patients have some very special problems: denial, high rates of suicide, anger, acceptance, accommodation, the tremendous financial burden, and problems of access to care for a long term chronic illness. In addition to the common problems of the terminally ill, the AIDS patients face stigma. It is socially acceptable to die from cancer or leukemia, but it's not socially acceptable to die from AIDS. So terminal sexually transmittable diseases present an additional factor not present in non-infectious diseases. They are important issues and they need to be addressed.

The critical period in this patient population is* before *they get sick and I think we're just on the brink of realizing that investing large amounts of money and effort at the end stage of the disease is inappropriate and nonproductive.

The emphasis on treatment is shifting to the latent period between infection and the time when the immune system starts to go. We have very little success in reversing the immune deficiency. We are learning, step by step, that it is critical to identify the patient early and to try to prevent the decomposition or the faulty mechanism of the immune system from breaking down. The critical period in this patient population is *before* they get sick and I think we're just on the brink of realizing that investing large amounts of money and effort at the end stage of the disease is inappropriate and nonproductive. That makes early detection extremely important and that, I think, is where the role of dentistry is: early detection and identification of these patients in order to begin initial therapy. AZT, one of the more promising drugs, tries in a sense to reconstitute the immune system. But you can't reconstitute a system that has vanished. Accordingly I think we're going to see that we need to make testing accessible, easy, and fast.

Bracing for the Long Haul

We do have to recognize that once we get into this business, there's no backing out. Once we open a clinic and begin to treat a patient population, this is not something we're going to do for three years or five years. This is a long haul proposition. Whatever process

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evolves in the state of Delaware, I hope from the experience that I've gone through, that I can persuade you to look as far ahead as you can and to design a system that you can live with, realizing that it will be in place for a very long time. The prospect for eliminating a sexually transmittable disease in our population once it's been introduced is virtually zero. This new illness is going to be a permanent part of pathology that calls for a little different thinking.

It has been our policy that this illness is a medical problem, an infectious disease. Servicemen who are found to have it are not disciplined. They are treated medically.

It has been our policy that this illness is a medical problem, an infectious disease. Servicemen who are found to have it are not disciplined. They are treated medically. They are to be treated, medically retired, and cared for by the government. What happened unexpectedly when we announced that policy was an inundation of enlistments. This patient population is very much aware of their problems, of the costs, and of the problem of access to care. If you serve 90 days of active duty you are a veteran, and the government then has to assume care for you. Many people were attempting desperately to get into the federal service because they had no idea how they were going to be able to provide care for themselves. Accordingly I want to point out to you that one of the unavoidable consequences of designing a system is that it will have an impact on attracting or deterring an influx of patients. That is both a political problem and a social problem — and an economic problem.

I want to make a final point. I think there is no difficulty in treating this patient population. I do feel that inevitably what will happen as a natural consequence and a natural course of clinic medicine is that these patients will be drawn to centers that have multidisciplinary approaches and are staffed to handle infectious disease. And that will happen because the access to care will be quicker, the care more thorough, and the follow-up more appropriate. And the patients will do much better. ■

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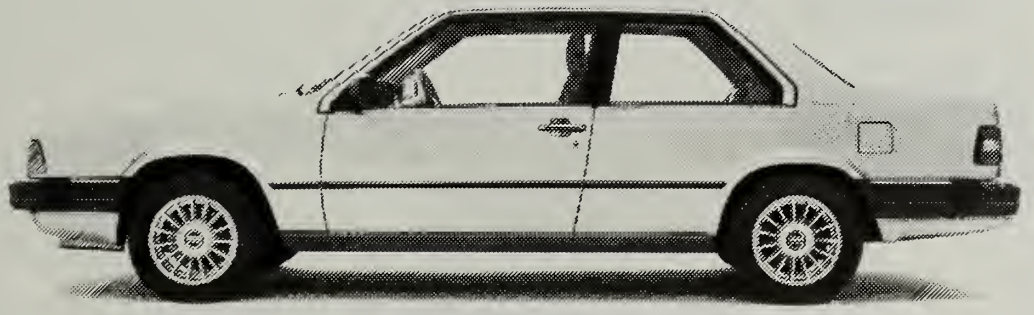

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The Researcher's Initiative

Robert R. Redfield

Dr. Robert Redfield, since 1986 Section Chief, Retrovirology at the Walter Reed Army Institute of Research, worked with Dr. Robert Gallo in discovering HIV. He has been responsible for AIDS laboratory research at Walter Reed and acted in the clinical treatment of AIDS patients at that institution.

The following is drawn from his remarks at the Professional Conference on AIDS held last April.

It is from my perspective as a doctor, as a researcher and as someone concerned about public health that I speak today. I want to go through some of the aspects of the clinical disease to make several points that I think are important in understanding the nature of this epidemic and where it is today. I shall also express my own opinions as a physician and a scientist concerned with public health as to how a medical community should respond to this epidemic.

When AIDS was first recognized it was a mysterious syndrome, an aggregate of signs and symptoms without an etiology. To the credit of the public health service in three short years it was no longer a mysterious *syndrome* but a *disease*, that is to say a disorder of bodily functions with a defined etiology. In 1984 we recognized that AIDS, the syndrome, was actually the end-stage clinical consequence of an infectious disease caused by a virus known as HIV. And now in 1988 we know probably more about the clinical pathogenesis and the clinical manifestation of this disease than we do of any other in clinical medicine.

In my opinion "AIDS" is really an anachronism we can really no longer afford to focus on in the medical community. We need to address HIV infection and the whole spectrum of illness it causes. HIV is a *retrovirus*. The power of a retrovirus and the reason that this epidemic is spreading so rapidly comes from a very important biological property of these viruses. When many viral diseases infect the cell or the host they replicate. There is an immune response to them, they are ridded, and the individual is then immune to them. When a retrovirus enters a cell, it actually becomes part of the genetic information of the cell in order to reproduce itself. What that means at the clinical level is that once a retrovirus infects a human being, it's really part of him for the rest of his life. A self-limited retrovirus infection is not consistent with the biological properties of these viruses. When they infect a human host they become part of the genetic information of that individual for life. We have understood that biological property from the beginning and it is very important in understanding the magnitude of this epidemic and how it is spreading throughout the world.

We also understand that when a retrovirus becomes part of the genetic information there is a period of time before there is an immune response: the presence of antibody directed against this virus. It's a marker that the individual is in fact infected with the virus itself. Back in 1984 when many people used to say that antibodies to the AIDS virus meant that you had been *exposed* to the AIDS virus, to those of us trained in retrovirology the presence of antibodies really meant that you were *infected* with the retrovirus. I think that in 1988 we all recognize that. Since 1984 we've had the ability to diagnose HIV infection, that is to say that an individual is infected with the virus *for life*.

We also know that the AIDS virus causes a disorder of a bodily function, the immune system. The T-4 cell which is the center of the immune system, or the quarterback of the immune system, is the primary target of the AIDS virus. The virus replicates in that cell and causes premature death. But the virus actually causes an immune defect throughout the entire immune system. Early in the disease, it causes abnormalities in the B cell system, the cells that make antibodies for your body's defenses. Clearly this virus causes disorder there. We've come to know that

the virus replicates very well in monocytes, in macrophages and tissue cells such as Langerhans cells, but from a clinical perspective the most important part of this disease is that it causes the premature destruction of the helper cell, a slow chronic process in the human host.

Once we understood the etiology and the central pathogenic event, the premature destruction of T cells, we tried to form a systematic way to look at this as a continuum. One can actually divide it into six stages of illness that are graded on the degree of immunologic dysfunction. It is very helpful in the clinical management of patients and we continue to use it four or five years after we developed it in our practice of medicine. It is also helpful in trying to understand the natural history of this infection.

If you look at the stages of illness there actually is a correlation between the destruction of T cells and the different stages of disease. The T cell number correlates with the clinical stage of disease. There's a gradual destruction of T cells and the clinical consequences are defects in ability to regulate infections at the level of skin, defects of protecting and regulating infections at the level of the mucous membranes, and finally defects at the systemic level where patients develop opportunistic infections.

One patient taught us very early that this virus infection takes a very long time from the initial infection to the time that an individual actually develops the clinical disease and dies. A young man who became infected in the summer to fall of 1980 had an acute mononucleosis-like syndrome, which, in retrospect, was probably the acute retrovirus syndrome. He developed chronic lymphadenopathy, which was well documented over the next three years with multiple lymph node biopsies. He then came to Walter Reed at a time when we were looking for patients with this new AIDS-like illness. We recognized that what these patients appeared to have was low T cells, and so, when we saw patients with lymphadenopathy we automatically worked them up for their T cell system. (We had an arbitrary definition of "AIDS related complex," which was less than 400 T helper cells and chronic lymphadenopathy for greater than three months.) Over time the patient developed what we call stage 4 disease—persistent defects of hypersensitivity, and then stage 5, which would be complete anergy for greater than three months. For 38 months this patient felt totally healthy. He was running 3 or 4 miles a day. You would have said that all of a sudden he developed AIDS. In reality if you had been following him from an immunological point of view and following what this virus was destroying, the T cell system, you would have predicted the progressive destruction of his immune system. He then developed cryptococcal meningitis and he died at 49 months of follow-up. For 68 months this man, classified as healthy, had a subclinical HIV infection, a clearly developed progressive disease.

In 1985 a San Francisco study said that only 10 percent of people that had a healthy adenopathy developed AIDS. This is consistent with our study. If you started at Walter Reed Stage 2 (which is chronic lymphadenopathy) and you followed for three years, only ten percent developed AIDS and only five percent actually died. But 75 percent were sicker in terms of their immunological function. Everybody became sicker in terms of immunological function. For example, if you started at Walter Reed Stage 3, 29 percent developed AIDS; at Walter Reed Stage 4, 71 percent. Or if you're one of the "healthy" with less than 400 T helper cells, 100 percent developed AIDS. This gives you an understanding of the natural history of infection: it is a *progressive* fatal disease that gradually destroys the T cell immune system in a majority, if not all, infected individuals.

There were five patients in the Walter Reed Stage 2 class who did not progress—their mean T cell count dropped from 875 to 525 in the follow-up period. So although (arbitrarily) they did not progress to Stage 3 disease they clearly suffered a significant destruction of the T cell systems.

Early on the virus replicates. Gradually it seems to be controlled to a degree. If you try to isolate virus from Walter Reed Stage 2 or 3 patients, in only 15 to 20 percent can you actually get the virus out, using crude techniques—(that's

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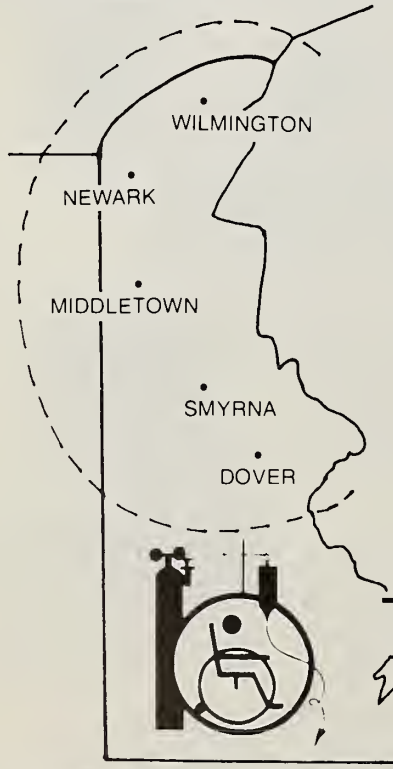
not to imply that if we don't try to use very special techniques we can't grow the virus)— but gradually over time the amount of virus in the individual host seems to go up. This is contrary to what many people believed two or three years ago. In patients toward the end of the illness, it's very easy to isolate the virus and there's a larger quantity of virus in patients as they develop more and more symptomatic disease. Many say, "there's no reason to know if I'm infected now, because I'm in a stable relationship." But over time there is a dynamic infectivity with the AIDS virus so that people are less infectious early in the disease when they have Walter Reed Stage 2 or 3 diseases. Later they become much more infectious. Accordingly a majority of those infected now are the least infectious they are going to be and they would benefit from an opportunity of knowing if they are infected or not. The immune system does respond to the virus and regulates and controls the infection. Indeed, every protective immune response that we know in infectious diseases has been demonstrated in HIV infection. I think that nature does have a normal immune response to this virus. The only problem is that this virus isn't like the others: it becomes part of the genetic information of the immune system itself and it gradually picks away until it destroys the immune system. I believe that in the next ten years or so, we will begin to understand this natural response and be able to mimic it, and use that as an effective intervention strategy in dealing with HIV infection. Many people consider that somewhat hypothetical at this point, but I think that's something we will accomplish.

As clinicians, we can clearly understand there is no mystery about the pathogenesis of this infection in the human host: it is a progressively fatal disease in a majority if not all of those infected.

It is a sexually transmitted disease. It is also transmitted by blood and blood products, but I'm going to discuss sexual transmission because I think that's the important role of transmission in this country today.

In 1985 vaginal-genital intercourse was proclaimed by many to be safe sexual practice. It was said that if one stayed away from unsafe sexual practices (e.g. anal intercourse), one could avoid infection. It was shown, however, in one study that 13 out of 16 in the study practicing what was considered safe vaginal-genital intercourse infected their partners. That's a highly efficient mode of transmission by recurrent sexual contact. The study also emphasized that condoms can reduce the risk of transmission. Only two of 12 individuals who used condoms every time infected their partners. I use the word "only" sarcastically, because I don't think that a 17 percent failure rate in the case of a fatal, sexually transmitted disease is reassuring.

Many people think the condom is the centerpiece of the public health effort to control AIDS. The FDA won't license the condom for birth control. Why? Because the condom fails 5 to 15 percent of the



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time. I think that we shouldn't assume that the condom is going to prevent the spread of a teeny little virus any better than it does a fairly large sperm cell that only can make a successful impregnation three or four days a month. So my position medically is that the condom has just too high a failure rate to be accepted as an optimal medical strategy or for us in the public health perspective to say this is the best we can do. On the other hand, I want people that do what I think is medically ill-advised or from a public health perspective ill-advised, to reduce the consequences of their action by wearing condoms. But I don't want them to feel good about it. I don't want them to think that they're doing what I think is right medically.

When we see patients who have Walter Reed Stage 1 or 2 disease and evaluate their spouses, only around 16 percent of their spouses are infected. But if they're at stage 5 or 6 disease it's on the order of around 56 to 60 percent. Studies of hemophiliacs, which used to be used to say that heterosexual risk was overestimated, now show that as the T cells go down below 200 in the male hemophiliacs the women are becoming infected. Actually there is a very nice relationship between degree of immunodeficiency and the ability to transmit this virus. That again tells us that we have a great opportunity: most Americans are less infectious to their partners now than they ever will be again, if we in the medical community, the legal community, and the legislative community can somehow figure out a way to get across to people the idea that they would *like* to know this information.

This is my simple message: it's a sexually transmitted disease. Any of you who are at risk for a sexually transmitted disease are at risk for the AIDS virus infection. Any of you that are never at risk for a sexually transmitted disease will not be at risk for the AIDS virus. Your children who are at risk for a sexually transmitted disease will probably be at risk for the AIDS virus, and those of your children who will never be at risk for a sexually transmitted disease, won't be. Twenty percent of adults by the age of 30 have seen Herpes Simplex II. By the age of 30, 40 to 60 percent of blacks have seen Herpes Simplex II. It's not because blacks or caucasians are promiscuous, it is because they slept with someone who had Herpes Simplex II. The AIDS virus will be no different.

I want my children to know whether their sexual partners are infected with the AIDS virus. If people want to have multiple sexual partners, or be homosexual, then they're not at risk for the AIDS virus as long as their partners are not infected. And I think that from a medical position, as a doctor, that's the position I try to teach: from a medical perspective people need to know whether their sexual partners are infected.

Heterosexuals at Risk

Masters and Johnson published a book that looked at heterosexuals who have had over 30 different sexual partners in the last five years. In the city of New York, ten percent of the women - were infected with the AIDS virus and eight percent of the men. People say that just couldn't be true or those are very active heterosexual people. That's right. That's what Masters and Johnson looked at - very active heterosexual people. Heterosexuals are clearly at risk. They're at risk if they sleep with those who are infected with the AIDS virus. They're not at risk if they sleep with those who are not infected.

There is only one risk group: human beings who have sex, share blood or blood products, or were born to parents with the AIDS virus. The whole notion of risk groups classification is totally inappropriate now, because it implies to young people that there's a risk group and there's a *not* risk group. I don't mind as long as we define the risk group as human beings who have sexual, parental, or perinatal exposure to the virus. The virus won't be generated spontaneously in the bedrooms of America. It's only going to occur in people who are exposed to it, but it's not a disease of gay men or drug addicts or hemophiliacs. It's a disease that people acquire because they're exposed to others carrying it.

Misplaced Emphases

Many people have said today that we need to stop talking about AIDS, *per se*. I agree. We need to recognize from the natural history of this infection, that it takes on the order of eight to twelve years from the time you're infected to the time you develop AIDS. The AIDS cases in Delaware today are people that

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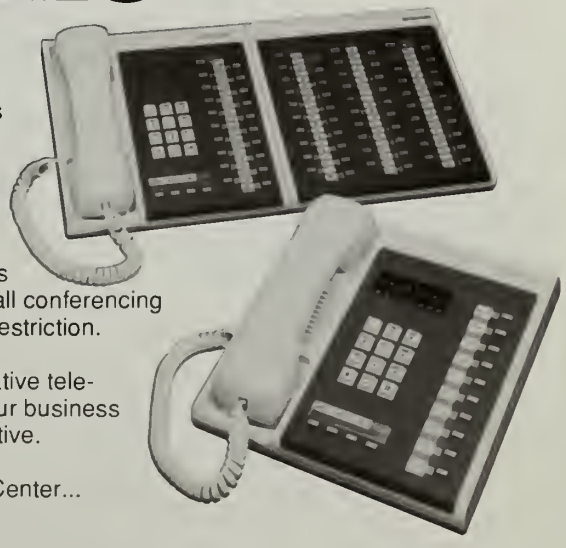

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Researcher's Initiative
(continued)

were infected in the 1970s, the late Carter years, maybe the *early* Carter years. The epidemiology of AIDS today (homosexual men and drug addicts) tells us nothing about how this virus is being transmitted. It tells us how the virus was being transmitted back in the late '70s. I am glad that someone is recording the historical perspective of this epidemic. But I don't want to see that done at the expense of not knowing where the epidemic is today. And the reality is that in many parts of the country we don't know where the epidemic is. We need to shift our focus from AIDS to HIV infection, from "risk groups" to exposure to the virus.

We've had the ability to make an accurate diagnosis through screening and confirmation tests since 1984. It can be done with a greater degree of sensitivity and specificity than we have in any other test in clinical medicine.

The Department of Defense program for young civilian applicants who wanted to join the military service incorporated an analysis for HIV infection into the medical exam. I have a great deal of pride in the way the Department of Defense has handled this—as a medical problem. When you want to join the armed forces, you're evaluated for your medical fitness for duty. HIV infection is considered to make you unfit for active duty for a 20-year military career. We do a screening (ELISA). If it's reactive we do a Western Blot. If it's positive by very specific criteria we obtain a second specimen. Why? When you're running 100,000 to 200,000 specimens a month it's much more likely to have a clerical error than a technical one. In my lab we found clerical errors in around 3 per thousand of the hepatitis B. serologies. We couldn't tolerate that for HIV infection. We require a second sample and if that sample is also positive the subject is informed that he is infected with HIV.

This is where the epidemic is among young people who want to join the service. You should remember that young men and women who want to join the service have to graduate from high school, they can have no records of felonies, and they must sign a statement saying they're not gay and that they don't use drugs. We select against some of the "higher risk behaviors" that people associate with HIV infection. On

the other hand, the military is probably made up of lower socio-economic groups. But over all, 1.5 per thousand of the young people who want to join the service are infected with the AIDS virus. We must put that in perspective. In San Francisco in 1975, less than one in one thousand gay men were infected; by 1985, 500 per thousand. How did that happen? It didn't happen because they were gay. It didn't happen because of anal intercourse. It happened because they had sex with people infected with the AIDS virus. It's very simple, very straightforward. Right now, 1.5 per thousand of the young people who want to serve their country are infected with the AIDS virus, a higher rate than obtained among gay men in 1975. Furthermore, there is an age related curve: among 25 year olds, it's 3 per thousand.

You in Delaware may think you don't rank high in the AIDS cases of America, but I can tell you in all the large scale studies that we've done through serological survey, Delaware ranks in the top five for prevalence of HIV infection.

You in Delaware may think you don't rank high in the AIDS cases of America, but I can tell you in all the large scale studies that we've done through serological survey, Delaware ranks in the top five for prevalence of HIV infection. Number one is New York where it's almost ½ percent of all men and women who want to join the service. Maryland, my state, ranks number two, New Jersey number three, and Delaware kind of sits in the middle and usually ranks fourth or fifth, ahead of California, ahead of Texas, and ahead of Florida, where many people think this epidemic is focal. Now when I go across the Mississippi, everyone tells me it's never going to happen in Montana, because people in Montana are different from those people who live on the East coast. I tell them that they have an opportunity to make an impact and use their knowledge, because I think it's going to happen in Montana. (I don't think Montana people are that different from those of us on the East coast.) When I talk to people on the East coast I tell them what our studies on Africa show. They reply, "Well, that's never going to happen in America because we people on the East coast are different from those Africans." I don't think we're that different from "those Africans," having been there and met them. This is where the epidemic is, and your state is in the middle of it.

Let's look at the Nation's capital. One in 200 teenagers from the District of Columbia who have graduated from high school, and who don't have felony records, are infected with the AIDS virus. The capital of the AIDS epidemic in young people who want to join the service is New York. We found that two percent of all male applicants and 1.8 percent of all female applicants from Manhattan were infected. In the New York metropolitan area it didn't matter if you were black or white, man or woman: your risk of infection depended upon whether you were 18 or 25. If you were 18 it was three per thousand; if you were 25 it was three percent. When the New York Commissioner of Health says he's surprised that one out of 43 women from the Bronx who elected to give birth to babies in the month of November, that one in 61 women from the city, and one in 112 women statewide were infected, it should come as no surprise. This epidemic has been moving in the young people in New York City for quite some time now.

You read in the papers that the epidemic is "stable." Not true. Again, I'm not worried about the epidemic in 40 to 60 year olds. I'm worried about 15 to 30 year olds, because that's where sexually transmitted diseases tend to be a problem. If you plot by age group the first two million people who elected to join the service, you can get an annual estimated incidence of what HIV infection is from one year to the next. That's what we did with our analysis of the military data of civilian applicants. We can now see the likelihood of infection from year to year. We have found that there is a 40 percent greater likelihood that a black or white man from a lower AIDS incidence area will be infected the second year over the first year. A doubling time of less than three years in young black and white men from low endemic areas would probably include Delaware and most of the United States. The situation of black women is even

(Continued on page 23)

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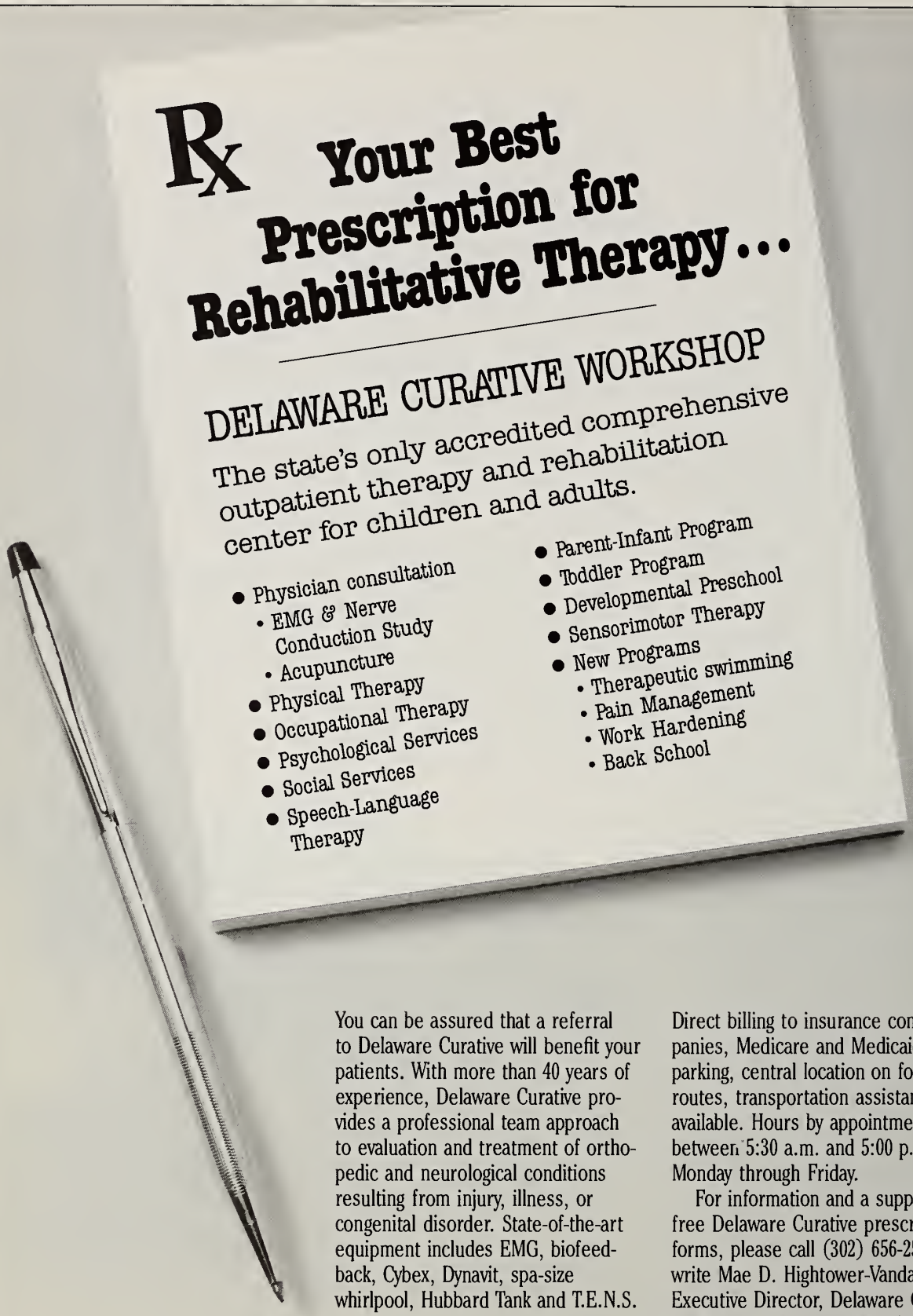

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more tragic. Most of the incidence cases I see right now both at Walter Reed and in my practice are black females. They're the most rapidly growing group in an endemic area. There's a 120 percent greater likelihood they're infected the second year over the first year. On the national level, the doubling time in black women who want to join the service right now is on the order of one year. I don't think it's because these women are black. I don't think it's because they're women. I think it's because they're being exposed to people who have the AIDS virus. I don't consider it a stable epidemic when black females are doubling in one year or when males and females, or males from around the United States are doubling in less than three years.

Since 1984 the medical community has had the opportunity to interrupt ignorant transmission among their patients. I think a lot of patients are going to be upset when they find that that right has been denied them because the medical community hasn't provided the leadership to establish early diagnosis of HIV infection.

In Praise of Knowledge

We have had a very aggressive clinical program in the military since 1984. I'm proud that the members of the armed forces and particularly the army, are provided the opportunity to receive medical care based on knowledge. I also think that soldiers should have the opportunity to stop ignorant transmission. Since 1984 the medical community has had the opportunity to interrupt ignorant transmission among their patients. I think a lot of patients are going to be upset when they find that that right has been denied them because the medical community hasn't provided the leadership to establish early diagnosis of HIV infection. All soldiers have the opportunity to be informed if they have been unknowingly exposed to it. One thing unique about the military is that we can practice medicine based on knowledge, independent of social and political pressures.

This is the medical agenda I should like to leave with you. HIV infection is no different from any other disease, and the principles of medicine should be practiced here. We strive for early diagnosis and we provide optimal care based on knowledge. We need to interrupt ignorant transmission and we physicians should be providing the leadership of our national response to a national crisis. We need to work with our legislators and, our lawyers, but medical people must provide the leadership for a medical problem. I say this, we are dealing with a *treatable* disease. Most people with HIV infection today are being denied optimal treatment because they don't even know they are infected. I can stop the leading cause of death, pneumococcal pneumonia, but I can't stop it if I don't know my patients are infected. I can optimize my medical care based on knowledge, but I can't do it if I don't know my patients are infected. I can actually interrupt ignorant transmission to their friends and families but I can't do it if I don't know they're infected. And unlike Dr. Day, I would not say just that the physicians have the *right* to know their patients are infected. My point is that physicians have the *responsibility* to know if their patients are infected, so that they can provide the medical care for which their patients look to them.

. . . medical people must provide the leadership for a medical problem. I say this, we are dealing with a treatable disease. Most people with HIV infection today are being denied optimal treatment because they don't even know they are infected. I can stop the leading cause of death, pneumococcal pneumonia, but I can't stop it if I don't know my patients are infected.

The Testing Issue

There are two approaches to medical link/test link education. One is what I call "volunteer testing with routine ignorance," and the other "routine testing with voluntary ignorance." Both are

(Continued on next page)

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Researcher's Initiative
(continued)

voluntary. I would rather put the routineness on what I think is medically correct: the early diagnosis of HIV infection. People should know and their doctors should help them know if they're infected. The argument against routine testing with voluntary ignorance stresses the stigma of disclosure. But is there more stigma when I have to go to a gay mens' health center and give the hidden code to find out if I'm HIV infected or if my doctor routinely did it and everybody knew? We have put the stigma on the person who knows. We should put it on the person who doesn't. Is it discriminatory to provide this knowledge to people who are already concerned enough that they come forward and seek and ask you to help them or they go to anonymous clinics? Or is it less discriminatory to provide an equal opportunity for *all* our patients? When you consider that this epidemic is moving rapidly now in the young black heterosexual population, you realize that our program today is very discriminatory. Education is critical. We have a program that's been in place for several years whereby people can come forward if they think they're at risk and get tested at anonymous test sites. They get educated. I'd rather educate *everybody*. Routine testing in a medical setting is a way to provide education to all, except to those who have been educated to a point where they don't want to know, because they're concerned. And then I'll try to educate them as to why their ignorance is hazardous to their health.

We think it's a good idea for people who are going to get married to know if they're marrying people with the AIDS virus. In the only state that's done premarital testing, one in 2,000 people has been found to be infected.

People have argued against premarital testing. And again, I think they miss the point. I think that this country has to create an environment in which everybody who is infected knows it in order to get optimal care and stop ignorant transmission. Everybody in this state needs to know about the AIDS virus and what it means, and their role in the epidemic. We think it's a good idea for people who are going to get married to know if they're marrying people with the AIDS virus. In the only state that's done premarital testing, one in 2,000 people has been found to be infected. People say that's not cost effective. I think it's pretty cost effective to be able to tell those one in 2,000 people that have a fatal virus so that they may not infect partners they're about to marry. The other argument that I would also use: What is the public health effort to control the epidemic among the American family of the future? One is to say, "It's not going to happen." The other is to encourage young men and

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women who are about to get married, since they are going to have recurring contact, to know whether this virus is going to be part of their relationship. It's a powerful educational tool and it only costs $6.00.

I can't prove these things, so I write them as assumptions because every time I'm in a panel discussion I am asked to prove them and I can't. I cannot prove that knowledge is better than ignorance. But I assume it. I cannot prove that compassion is better than vengeance. I have been asked to prove it. I can't. And I cannot prove that respect is better than fear, but I think these principles are the principles behind any medical, legal, legislative, public health policy that we should have in dealing with this epidemic. We should not assume that ignorance is better than knowledge, or that vengeance is better than compassion, or fear is better than respect.

We know all about this disease. We have all the tools we need to deal with it. We have a number of alibis that say we can't use these tools. It's obviously my position that no matter how excellent the alibis, we know enough now to make a major impact on this epidemic among the young people in our country. We just have to have the courage and will to use it. We in the medical community need to work with our lawyer friends and legislators to come up with a program that will begin to utilize the opportunity, not the burden, that the scientific community has given us to watch this virus become endemic in the human species.

In reality the AIDS epidemic that I'm trying to stop is the AIDS epidemic of the 21st century. The crisis now is not the AIDS epidemic at the end of *this* century. That's already happened. We will make no impact on the AIDS epidemic in the State of Delaware for the next ten years, except for newborn babies. The impact we're going to make is in the AIDS epidemic of the 21st century. We know a lot about this progressive uniformly fatal disease. Our focus should be on the virus and, if the epidemic of this century has happened, we need to get together to form the policies to deal with the epidemic of the next. ■

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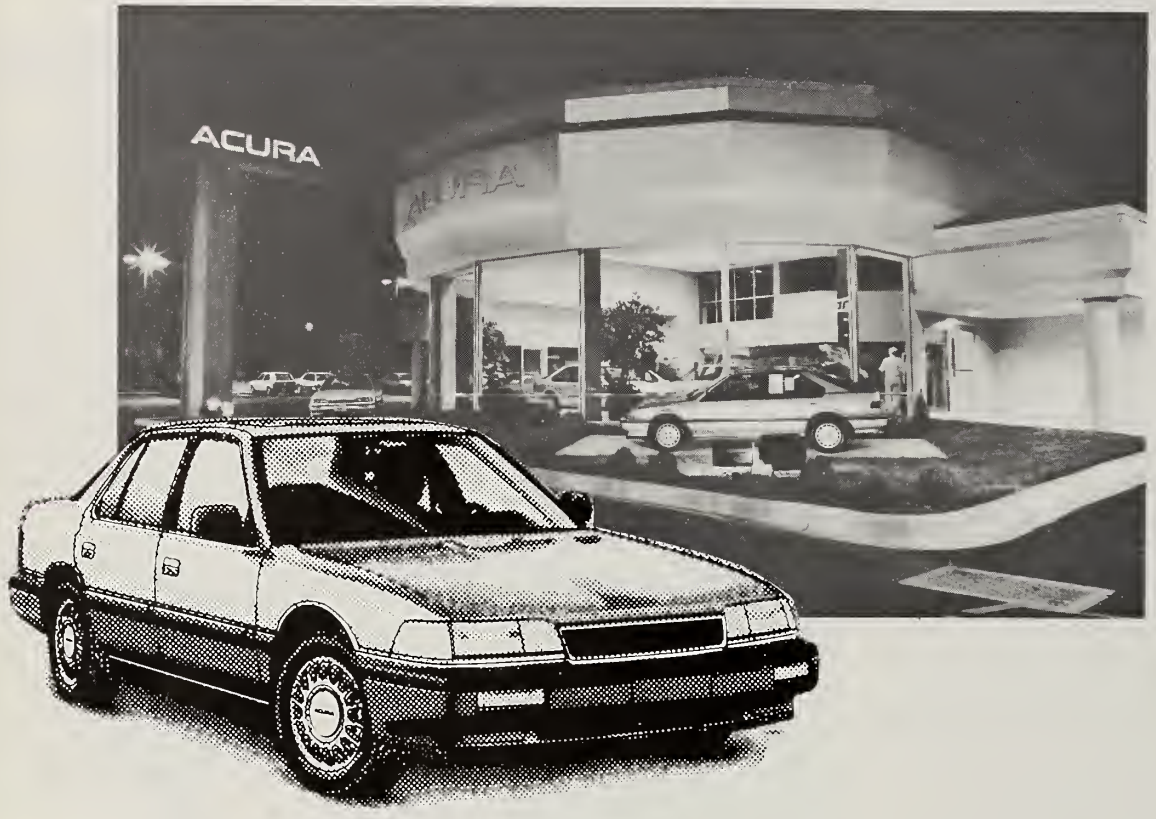

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Considerations and Potential Pitfalls in Lab Tests for AIDS

Cyril H. Wecht

The use of laboratory testing in establishing a diagnosis of AIDS and ARC has become increasingly important in the last three years. Since the initial commercial introduction of testing kits in 1985, there has been a great deal of controversy surrounding the proper use of these procedures. Many questions have been raised about the sensitivity and specificity of the various commercial kits that are in use. Each innovative development that increases the ability of testing to identify previously undetectable levels of the AIDS virus antibody is hailed by its developers as a new benchmark reference method, one that will allow us to define the true scope of the infection.[1,2] Indeed, are we following correct procedure by screening only for the HIV-1 virus? Do we need to concern ourselves with the recently identified HIV-2 as a potential source of infection, a somewhat less virulent virus described by Dr. Peter Piot, a Belgian AIDS researcher, at the recently concluded Stockholm conference?[3]

As the debate on various legal and ethical issues continues, we as medical professionals are faced with the reality and necessity of performing AIDS testing and interpreting the results with test methods that are less than perfect in an attempt to provide realistic estimates of the true nature and extent of the disease.

The most recent CDC criteria for AIDS case definition partially categorize individuals on the basis of laboratory test results.[4,5,6] I should like to define and discuss the problems associated with the laboratory performance of AIDS tests.

Terms Related to AIDS Testing

FALSE POSITIVE: A positive test result is obtained in the absence of the AIDS virus. This results in an individual's being incorrectly categorized as having the antibody to the AIDS virus when it is absent. This generally results from a lack of specificity in the test system.

FALSE NEGATIVE: A negative result is obtained in the presence of the antibody to the AIDS virus. This results in an individual's being incorrectly classified as virus free when he does indeed have virus present. This can result basically because of one of two reasons:

1. The individual being tested has not developed detectable levels of antibody, i.e., the levels of circulating antibody are too low for the test kit to detect.

2. The test method being used lacks sufficient sensitivity to detect circulating antibody levels, even though they are present in sufficient quantities.

TRUE POSITIVE: A positive test result is obtained on a patient that has the antibody to the AIDS virus.

TRUE NEGATIVE: A negative test result is obtained on a patient that lacks the antibody to the AIDS virus.

REPRODUCIBLY REACTIVE: When a specimen is found to exhibit a positive result upon initial testing, it must be retested. If it is found to be reactive a second time, it is classified as reproducibly reactive.

SENSITIVITY: This is the ability of the test procedure to identify the AIDS antibody in those possessing the disease. Ideally, sensitivity should be 100%, i.e., if 100 patients with AIDS are tested, 100 positive test results will be obtained.

SPECIFICITY: The test procedure will correctly classify as negative all individuals who do not have the AIDS antibody. As with sensitivity, specificity should be 100%, i.e., if 100 individuals who are disease free are tested, 100 negative test results will be obtained.

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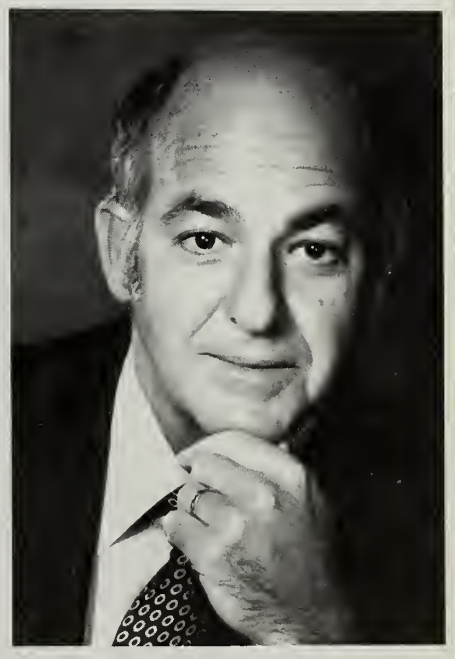

Cyril Wecht brings the disciplines and expert knowledge of both the medical and legal professions to the discussion we are privileged to publish here. Dr. Wecht is today Adjunct Associate Professor of Epidemiology, University of Pittsburgh Graduate School of Public Health and Adjunct Professor of Law at Duquesne University of Law. He is a member of the Pennsylvania Bar and holds medical licenses in Pennsylvania, California, and Maryland. He is also the author of an exceptionally large body of medical-legal literature.

Dr. Wecht's remarks were delivered in July at an AIDS conference in Arlington, Virginia sponsored by the American College of Legal Medicine.

Lab Tests for AIDS
(continued)

PREDICTIVE VALUE: This is an overall measure of a test method's ability to correctly classify diseased individuals as possessing the AIDS antibody and disease free individuals as lacking the AIDS antibody. An ideal AIDS test would be 100% sensitive and 100% specific and would have a predictive value of 1.00.

The most commonly used method of testing for the AIDS virus antibody is the Enzyme Immunoassay (EIA or ELISA) technique. Of 698 laboratories reporting data to the American Association of Blood Banks and the College of American Pathologists, 610 or 87.4% use an ELISA method. Six ELISA test manufacturers are reported. A total of 88 laboratories reported performing Western Blot testing for the AIDS virus antibody.

Each of the six manufacturers addresses the limitations of its particular test procedure in an attempt to make users aware of the precise purpose of the test results that have been generated. These limitations are very consistent from manufacturer to manufacturer. For example, EIA procedure and the interpretation of results must be closely followed when testing serum and plasma specimens for the presence of antibody to HIV.

The primary use of the HIV antibody test is to screen blood and plasma donations so that units containing antibody can be identified and eliminated or restricted to further manufacturing into non-injectable products. It is inappropriate to use this test as a screen for AIDS or as a screen for members of groups at increased risk for AIDS in the general population. The presence of HIV antibody is *not* a diagnosis of AIDS. Individual blood and plasma donors who are repeatedly reactive for HIV antibody should be referred for medical evaluation, which may include additional testing such as antibody detection by the Western Blot technique, if that has not been done at the collecting facility.

A negative test result does not exclude the possibility of exposure to or infection with HIV.

False positive test results can be expected with a test kit of this nature. The proportion of reactives that are falsely reactive will depend on the sensitivity and specificity of the test kit and on the prevalence of HIV antibody in the population to be screened.[7]

The prevalence of HIV antibody in random donors is not known, but the higher the prevalence of HIV antibody in a population, the lower the proportion of falsely reactive samples.

All estimates that are made of sensitivity and specificity are based on estimated prevalence rates. If these prevalence rates are in error, significant deviations in the false positive rates for all manufacturers may be found.

The use of the EIA or ELISA methods for the detection of antibodies is a well-established technique in the clinical laboratory, and one that presents no unique technical problems. As with all laboratory testing procedures, the general rules of good quality control apply. Complete and detailed records of all testing must be maintained. These should document all procedural steps

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used in reaching a final test result. All waterbaths used for incubation should have temperatures checked with each use, and all optical density readings should be recorded for both positive and negative controls and test specimens. All spectrophotometric equipment should be properly maintained, and written records of periodic wavelength checks and maintenance functions should be available. The specific details of the manufacturer's procedure should be followed exactly. Deviation from the written protocols can significantly influence final test results. The results of all testing should be reviewed by the supervising pathologist, and this review should be done with each testing run performed. Interpretive guidelines should be strictly adhered to, and repeats should be done as per the manufacturer's suggestions. If these guidelines are adhered to, the technical performance of the HIV antibody testing should present no unexpected difficulties in the laboratory. It should be stressed that all commercially licensed procedures have undergone the same FDA review criteria.

Once kit selection procedures have been completed, one should carefully review all protocols relating to infection control and contaminated waste disposal. While it is an infrequent occurrence, cases have been reported that would seem to indicate that exposure and subsequent infection have resulted from accidental laboratory exposure.[8] It will be necessary to establish appropriate training and education programs for all staff members who may come into contact with potentially hazardous materials. Training programs should not be limited to the laboratory staff only. Others within the organization can contact potentially infectious material and may be at risk. The need to address these issues involves not only good laboratory practice, but is also mandated by OSHA. On October 30, 1987, the U.S. Departments of Labor and Health and Human Services published in the Federal Register and mailed to over 500,000 employers a Joint Advisory Notice entitled "Protection Against Occupational Exposure to Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV)". It advised employers that they were responsible for the following:

1. Provide training and education programs for staff with potential exposure.
2. Adopt appropriate sanitation control procedures.
3. Develop standard operating procedures to reduce exposure.
4. Provide appropriate personal protective equipment.
5. Provide testing and other medical services to employees that may have been exposed.
6. Maintain a system of record keeping to document compliance with the above listed.[9]

The notice further announced that OSHA was beginning a program of enforcement, including inspections, to enforce its existing general regulations and statutory provisions regarding the duty of an employer to provide a safe and healthy work environment. Recent inspections conducted by OSHA of health care facilities have resulted in actions being taken against the employers. Fines that have ranged up to $5,000.00 have been levied in several cases.[10]

With the initiation of testing protocols, the laboratory assumes a major role as the provider of information to the medical practitioners requesting the HIV antibody testing. It is perhaps in this area that the greatest risks for liability are found. The pathologist must ensure that the requesting practitioner is aware of the meaning of the HIV antibody test. Failure to provide the practitioner with this information could result in the erroneous interpretation of data. Every attempt should be made to discuss the issues of sensitivity and specificity. A full understanding of these issues can significantly alter the information that is presented to a patient with either a positive or negative test result. One should be prepared to recommend the appropriate follow-up studies that would be needed to confirm or rule out a diagnosis of AIDS. Western Blot techniques are strongly suggested as a confirmation technique for the initial EIA positive findings.[11]

A newly developed test has been recommended as a replacement of the Western Blot test. The HIVAGEN test for HIV antibodies is a dramatic improvement over the Western Blot procedure and will soon replace it as the standard confirmation test for the detection of antibodies to the human immunodeficiency virus, a top AIDS researcher announced recently.

Everyone involved with HIV testing recognizes the shortcomings of the

(Continued on next page)

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Lab Tests for AIDS
(continued)

Western Blot assay. This test was selected for use because it was the only confirmatory test available in March of 1985 when widespread HIV testing of the nation's blood supply was initiated. However, the Western Blot is labor intensive, nearly impossible to standardize and clearly unsuitable for mass screening ventures.

A major problem with current testing procedures is indeterminate results on confirmatory testing. All positive results with the screening ELISA must be confirmed with another test, but the Western Blot has a 10 to 15% indeterminate rate.

These indeterminate results must be resolved by further testing. Superficially, this does not appear to be a major medical problem. However, it poses many serious difficulties.

What does an indeterminate result mean to a specific patient? What about a couple planning to marry who must obtain HIV testing beforehand as is now required by some states? Imagine the anguish of this couple faced with an indeterminate test result, particularly one that may take weeks or months to resolve.

This year approximately 29 million AIDS tests will be performed in the United States. Of these, about 500,000 will appear reactive on the initial screening and require confirmatory testing.

Using the Western Blot technology in confirmatory testing, approximately 75,000 results will be indeterminate and several thousand false-positive. This means 75,000 people will be told, "We don't know whether or not you have been infected by the AIDS virus." Even worse, some people will be told they are infected when, in fact, they are not.

HIVAGEN uses an ELISA technology —the same laboratory technology used in the successful AIDS antibody screen. Because of this approach, HIVAGEN is objective and automated as opposed to the subjective and manual Western Blot procedure.

Most important, HIVAGEN uses genetically engineered ELISA capture antigens. The capture antigens attract and bind the AIDS antibodies in the assay. The highly purified genetically engineered capture antigens give HIVAGEN a high degree of accuracy and reliability. The Western Blot has limited accuracy because the capture antigens it uses are from disrupted virus particles and are only partially purified and therefore contain human cell remnants that can interfere with the assay.

The diagnostic protocol for AIDS antibody testing is a two-step process—a screening test and a confirmatory test. If the screening test is reactive, a second screening test is performed to determine if the specimen is repeatedly reactive. The screening tests are highly sensitive in order to eliminate false-negative results. The screening tests are so sensitive, they may lead to reactive results in certain people who do not have the AIDS antibodies, e.g., lupus patients or women who have had multiple pregnancies.

Because of this, all repeatedly reactive screening tests have been confirmed using a confirmatory test—the Western Blot—which is far more specific than the screening tests and usually eliminates most false-positive results.

However, the Western Blot has several major limitations. First, the Western Blot is not a standardized test. With over 1,200 laboratories performing the Western Blot in the United States, there is a wide range in the quality of laboratory results. Second, the Western Blot is manual and requires subjective interpretation by highly skilled laboratory technicians. Third, nonspecific bands frequently appear in the test strips. As a result of these major limitations there are still some false-positive results.

In clinical trials of blood donated by healthy (AIDS-free) individuals, HIVAGEN produced no false-positive results. The Western Blot false-positive rate was 0 to 5% depending on who was doing the test and the type of Western Blot used.

In addition, HIVAGEN reduced the number of indeterminate results by 77% — 4.2% for HIVAGEN vs. 18% for a licensed Western Blot procedure.

In a series of over 1,200 individuals known positive for the AIDS antibody, HIVAGEN produced no false-negative results. HIVAGEN reduced the number of indeterminate results, this time by 84% — 2.5% vs. 15.6%.[12]

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Informed Consent

The laboratory should aid in the development of informed consent documents to be used by all practitioners that have requested HIV antibody testing on a patient. The joint development of these documents will protect both the practitioner and the laboratory.

The laboratory must address the issue of confidentiality of records and results when testing for the HIV antibody. Confidentiality of all laboratory records is a given; however, in the case of HIV testing, one would be well advised to take additional measures to preserve patient confidentiality. It would not be inappropriate to consider placing the actual testing logs and patient records in separate files. Access to these files should be restricted on a need-to-know basis.

The laboratory would do well to consider the potential for liability involved with general screening programs that may be proposed by various groups. It has been generally held that these screening programs (particularly of low risk employee groups) are an inappropriate use for the HIV antibody test. While the financial rewards of this type of testing program may appear to be very attractive, the potential for misuse and misinterpretation of the results weigh heavily in favor of not becoming involved. There is an increasing trend in the insurance industry to require HIV antibody screening as part of routine application procedures for life insurance, due in part to the losses that have been suffered. It has been estimated that the total dollar payout for AIDS-related death, disability, and treatment claims in 1986 was approximately $292 million.[13] The potential for litigious actions being brought against the testing laboratories is not insignificant.

The laboratory has a responsibility to report the results of positive HIV antibody tests to the appropriate public health agencies. Failure to report the results of these tests could result in fines and jail sentences. Similarly, the laboratory's failure to report a positive HIV antibody may create liability to third persons where it can be shown that if such a report had been filed, the third party could have obtained medical treatment that would have decreased pain and suffering and possibly prolonged life. This may prove to be the case where public health regulations provide for contact tracing of sexual partners of persons with AIDS. The people traced via this route could then be informed of available medical treatment and proper personal health care. This would thus decrease their likelihood of developing AIDS, or at least allow them to minimize the risks associated with possible opportunistic infections, etc.[14]

Specific Recommendations and Suggested Policies

1. No testing should be performed without verification of informed consent.
2. Oral requests for HIV antibody testing should not be accepted. Only those requests that can be shown to have originated with appropriate informed consent should be accepted for analysis.
3. These documents should be maintained by the requesting clinician. The laboratory should receive verification that bears the signature of the physician, but not the signature of the patient.

(Continued on next page)

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Lab Tests for AIDS
(continued)

4. Whenever and wherever practical, patient identification should be accomplished without the use of names. It is suggested that special request forms be developed that provide the laboratory staff with only alpha numeric code numbers.

5. All records bearing identifiable patient information should be maintained in locked files. Access should be restricted and on a need-to-know basis only. Access logs should be maintained and periodically reviewed.

6. The laboratory should provide the practitioner with necessary documents to ensure compliance with public health reporting regulations. Complete all information by code number and instruct the attending physician to provide patient specific data.

7. Review with the clinician the specific information needed for insurance claim processing. This should be reviewed with the patient, along with the specific meaning of the release of information statements that accompany most insurance forms. The patient should then decide if insurance billing is appropriate for this particular test.

8. All documents associated with insurance claim processing should be maintained under lock and key as in (5) above.

9. Develop and maintain strict staff educational guidelines to comply with the OSHA standards. Document your compliance in writing. Maintain these records.

10. Decide in advance specific procedures that will be taken in the event that an accidental exposure occurs to a staff member. In the event of an exposure, document all steps taken and all procedures carried out. Maintain these records indefinitely.

11. Establish strict sanitation and waste disposal policies in writing. Monitor these on an ongoing basis to ensure compliance.

12. Monitor the ongoing performance of the actual assay. Monitoring should be internal (i.e., rates of false positives versus true positives, etc.), external (through peer group comparisons using survey material), and through published performance reviews in the literature. Do not hesitate to revise procedures and make changes when they become necessary.

Summary and Conclusions

The laboratory testing for HIV antibody presents a unique set of challenges for the laboratory professional. These challenges have evolved from two separate sources.

The technical challenge of selecting, evaluating, and identifying the optimal testing methods by which the medical community at large can begin to identify the true nature and scope of the disease process. We are dealing with an imperfect test method. The prevalence rate in the population at large has yet to be fully defined. Rates of false positives and false negatives are given as statistical best estimates based on estimates of prevalence rates. We are facing increasing pressures from individuals and groups to screen large segments of the population. These same individuals and groups have not taken the time to review the very basic scientific and statistical data, which indicate that mass screening of the population at large is inappropriate. Until such time as the available testing methods are improved, and the rates of false positive and false negative tests are decreased, the dilemma will persist.

We also face the challenge of education. We are deluged with new information daily. We must digest this information and provide it to our fellow practitioners in a usable format. The concepts of specificity, sensitivity, and predictive value are not new to the laboratory field. They have been in use for many years. Unfortunately, they have been used too little outside the laboratory. With the onset of the AIDS epidemic, they have been catapulted to a sudden role of prominence. We have a responsibility to teach and educate both our fellow professionals and the public what these test results mean. When and where is it appropriate to test? These are questions that must be addressed.

The performance of these tests can subject the laboratory to an increased risk of litigation. We have a responsibility to ensure that we take appropriate steps to limit this risk. Never have staff training and education been as important. It is only through continuing and intensive efforts to maintain the absolute highest standards of testing accuracy and integrity that we can limit these risks.

The legal issues remain to be fully defined. Legislative actions are pending that will help clarify some of the issues of confidentiality, but these await final action. In the meantime, we must take appropriate steps to ensure that we limit our own liability. At the same time, we have an ethical responsibility to protect the rights of our patients. We must each take whatever small steps we can to enlarge the existing knowledge base about the disease. ■

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[3]"Largest AIDS Parley Ends in Stockholm", *New York Times*, June 17, 1988, p. 10.

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[10]Hermann, Donald H.J.: "Liability Related to Diagnosis and Transmission of AIDS", Law, Medicine and Health Care, Vol. 15, Summer 1987, pp. 36-45.

[11]"Serological Diagnosis of Human Immunodeficiency Virus Infection by Western Blot Testing", JAMA, Vol. 260, No. 5, Aug. 5, 1988, pp. 674-679.

[12]"Clinical Laboratory Update", Smith Kline Bio-Science Laboratories, Vol. 1, No. 3, May/June 1988, p. 1.

[13]"Insurance Companies Pay $292 Million for AIDS", Pennsylvania Medicine, February 1988, p. 24.

[14]"Partner Notification for Preventing Human Immunodeficiency Virus (HIV) Infection — Colorado, Idaho, South Carolina, Virginia", Leads from the MMWR, JAMA, Vol. 260, No. 5, Aug. 5, 1988, pp. 613-615.

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The Informed Professional: Another View of HIV Testing

An Interview with Dr. Lorraine Day

The report of the Delaware Division of Public Health's AIDS Advisory Task Force announces with the cozy insouciance of an armchair General that health care workers "intimately exposed to bodily fluids of patients, [are] at extremely low risk for AIDS." Report, page 4. The prospect to those in the trenches is somewhat less cheery.

One of the speakers at the Professional Conference last April, Dr. Lorraine J. Day, practices an exceptionally sanguinary kind of surgery at San Francisco General Hospital: she is an orthopaedic surgeon.

"We are covered with blood constantly when taking care of trauma patients. It's not uncommon to take care of a patient who bleeds fifty or sixty units and generally all over us. The most blood replacement I've even given to a patient that I've taken care of was 247 units. That blood goes into the patient and bleeds back out again. Many times after long cases, before we were aware of the risk, I had blood all the way through my underwear on to my skin, all over my abdomen, all over my legs. I've had to put my legs into the shower to wash the blood off. This is how life really is in the orthopaedic operating room in a trauma hospital."

Remember that Dr. Day practices in San Francisco, where the incidence of HIV infection is extremely high. Since she operates regularly on patients carrying the virus, she feels herself at risk. Exposed daily and for long stretches to large amounts of blood in such a community, Dr. Day is skeptical of the orthodoxy quoted above from the Task Force Report.

Her credentials make her an impressive dissenter: in addition to serving as Chief of the Department of Orthopaedic Surgery at her hospital, she is an Associate Professor at the University of California School of Medicine. Her intelligent and courageous determination not to accept on faith or authority the assertion that her risk is minimal has earned her much opprobrium: resentment of her message may arise from a fear of discrimination, which prompts many to resist anything remotely suggesting isolation, segregation, or lazaret mentality.

Dr. Day has encountered hostility in the community she serves, and she met it again in Delaware. (See "Plague Politics" *infra.*) Since her views are the product of a superior intellect at work on an accumulation of first hand experience, they're entitled to be heard, no matter how distasteful they may be to those who for ideological purposes minimize the danger to health care professionals.

Until early October last year Dr. Day and her colleagues believed that AIDS was not very contagious and that they were not at risk. There had been eight hundred needle sticks with AIDS blood at the hospital where she practices and no one had contracted the disease. Then she learned of a health worker who had originally tested negative for HIV infection, and who had no other risk factors. After a single accidental needle stick the worker turned antibody positive within six weeks. Faced with this alarming development, she met with all of the Chiefs of Service at the hospital, who agreed with her that routine voluntary testing of surgical patients was reasonable, and such testing began. She also took the position that she had an obligation to be tested herself. (If she should be positive, sustain a cut in the operating room, and bleed into a patient, the patient's infection would be her moral responsibility.) She is highly critical of doctors who refuse to be tested. She sees the present crisis as the occasion for reciprocal candor between health care worker and patient in the interest of informed precaution on behalf of anyone at risk in a surgical setting. She was tested and encouraged her staff to be. At that time the Chiefs of Services agreed that this was a rational thing to do. When this information hit the newspapers, there was an uproar, and many of her previous supporters backed down and disagreed with the position they had previously endorsed.

Dr. Day asked a pointed question about the received wisdom that the risk to health care workers is low. Low in comparison to what? Hospitals take extraordinary and elaborate precautions to protect people who handle fluoroscopy or x-rays in the operating room. Yet Dr. Day knows of no one who has sickened or died from the effects of these procedures for the last fifty years. If the "low risk" is about one in 800, (800 needle sticks before contracting an incurable infection) how should hospital workers react to the prospect of being electrocuted only once in 800 uses of sophisticated electronic equipment in the surgical setting? So high a prospect of lethal exposure would hardly be countenanced in the most slovenly medical setting.

(Continued on next page)

The Informed Professional
(continued)

The news got worse: in January 1988 Dr. Day learned of a laboratory maintenance man who contracted the virus. The initial response was to question his lifestyle, but he denied his exposure to any of the conventional risk factors. He had always worked with protective gloves. His virus was subtyped and found to be exactly the same type used in the laboratory.

The bad news continues to accumulate: a study in the Journal of Investigative Dermatology observes: *"The previous assumption that HIV infection can exclusively occur by the entry of virus through wounds in the skin and mucous membranes into the blood can no longer be considered valid. Our results suggest that the Langerhans cells in the skin and mucous membrane are primary target cells for sexually transmitted HIV infection."*

To Dr. Day this suggests points of entry in the eye, the mouth, the vaginal tract, the rectal tract, or the skin *without a cut or any wound.* She is understandably distressed that she cannot require that patients be tested, even though she must operate on them and risk exposure to their blood.

"We can stop drunk drivers in California and check them for sobriety. If they get caught it has major implications for them, sometimes their jobs and their social status. The Supreme Court has decided that the public good is greater than the disadvantage of the individual. And yet, we have people out there who can kill others with their disease, but we cannot routinely test them. It is said that the consequences of a false-positive test are too great to warrant routine testing. Nonetheless, ten million blood donors and two million military recruits have been tested and they seem to have handled the possibility of false-positive results."

The Fallacy of Universal Precaution

To get around the politically hot potato of testing, many in the medical establishment take the position that it is unnecessary to know the HIV status of each patient, because precautions can be taken in every case. Dr. Day doesn't buy this. "You can't play the Super Bowl every Sunday. There is no way you can

continue with that high level of anxiety every time you operate. The idea of using universal precautions is very high sounding but it's not realistic." She describes the almost unmanageable complexity of splash shields, inadequate supplies of properly sized surgical gloves, cumbersome knee boots (two pairs — they aren't water proof), surgical masks insufficient to filter out

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During the question and answer period at the Professional Conference a woman identifying herself as a lawyer from Philadelphia expressed concern for health care workers who don't have the same options as doctors.

Dr. Day's response: "I know that nurses and others in the hospital are at risk. When you're taking care of any patient with a contagious disease it is routine to take precautions. Two to three years ago at San Francisco General Hospital a number of nurses wanted to wear masks and gloves when they took care of AIDS patients. They were told they could not do this because it hurt the delicate psyches of the AIDS patients and that they would feel they were unclean. The nurses continued to wear gloves and masks and they were called on the carpet, taken down to the Civil Service Commission, and penalized." This is surely the height of goofy solicitude. Health care workers are engaged to practice effective medicine. They aren't on the contagion firing line (we apologize to Emily Dickinson) to help fainting robins back to their nests again.

aerosolized particles capable of carrying the virus, and a panoply of Star Wars contraptions that make it difficult for a surgeon to breathe or to hear what is being said to him. Major precautions like these are for the identifiably contagious (if you're allowed to identify).

Dr. Day is a eloquent spokesman for medicine first, ideology second.

"We have to go back to basics. The fear of becoming called bigots has caused us to lose our common sense. It's unfortunate that AIDS has been politicized. If it had started out as a truly medical disease and not a political one, we would have routine testing. During the polio epidemic, no polio patient wanted to keep secret from his doctor that he had the disease. If a polio patient was contagious and required an operation, major precautions could be taken, because all concerned knew what they were dealing with.

It is a sad time when we in the medical profession cannot voice our opinions. We must get this disease under control. We must save all lives. Gay, straight, minority, majority. The way to do it is to have routine testing of anyone who needs testing. We must put a lot of resources towards preventing the disease, as well as treating it. Until then we shall do nothing but keep our heads in the sand."

A lot of other people seem to share Dr. Day's concern. It is estimated that by the mid-1990's when the AIDS epidemic is scheduled to reach a rolling boil there may be a shortage of half a million nurses, and applications to medical schools are already falling off. This is hardly surprising. It is one thing to expect health care workers to be altruistic in the assumption of understood risks; it is quite another to demand of them a suicidal commitment to noble ignorance.

Ellen Goodman, the nationally syndicated columnist, who has also interviewed Dr. Day, made a shrewd observation, "If we are going to trust health care professionals to treat the sick, part of that trust is to give them privileged information, the tools of their job." ■

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Psychiatric and Psychological Aspects of AIDS

David E. Raskin, M.D.

Acquired Immune Deficiency Syndrome is defined by a disturbance in cell mediated immunity (one mechanism the body has available to combat infection). The incidence of this disorder has steadily increased through the 80s. High risk groups include homosexual and bisexual men, intravenous drug abusers, hemophiliacs, children of high risk parents, and female sexual partners of men with AIDS. There have been some reports of female to male transmission. Transmission usually occurs through bodily fluids and usually as the result of, a.) sexual contact, b.) blood transfusion, c.) The use of syringes contaminated with the virus, d.) or transmission from mothers to newborns.

The onset of AIDS is often signaled by the development of Kaposi's sarcoma, lymphomas, or opportunistic infections. Kaposi's sarcoma is a malignant tumor. Lymphoma is a tumor of lymphatic tissues. Opportunistic infections are those induced by organisms incapable of causing disease in a normal person but able to produce infections in a less resistant or injured host. Initial symptoms usually include, cough, shortness of breath, fatigue, diarrhea, weight loss or lymphadenopathy (swollen lymph nodes). Occasionally, the diagnosis of AIDS is made in a patient in whom depressive illnesses predate these physical illnesses. It is now apparent that there are psychiatric manifestations of AIDS, and there have been several papers reporting them.

Obsessional Symptoms Relating to Fears About Developing AIDS[1]

The Worried Well

Members of high risk groups concerned about developing AIDS encounter considerable emotional distress. Their symptoms range from obsessional worries to anxiety and panic attacks, and acute hypochondriasis (fear of illness). At times, these symptoms can reach the level of being dysfunctional and require psychiatric intervention. Psychiatrists have even treated individuals not in high risk groups who, because of a single sexual indiscretion, become obsessed with the fear of developing AIDS and who consult physicians repeatedly and request repeated testing as a way to reassure themselves that they have not been exposed to the AIDS virus.

Psychiatric Symptoms in People Diagnosed as having been Exposed to the AIDS Virus

The first set of symptoms are those that follow the disclosure that a patient has been exposed to the AIDS virus. As with other chronic diseases, the patient first expresses denial and disbelief. This is followed by depression or symptoms of anxiety. Thoughts of suicide are common. Suicidal behavior is more probable in AIDS patients with a history of documented personality disorders.

The second major variety of psychiatric symptoms are those relating to the direct effect of the AIDS virus on brain function.[2] Approximately 30 to 40 percent of patients with AIDS show symptoms of central nervous system impairment. Eighty percent (80%) demonstrate postmortem neuropathological abnormalities. The most common form of central nervous system dysfunction is a diffuse encephalopathy. Encephalopathy means a disease of the brain. Symptoms include malaise, lethargy, anorexia, and diarrhea, resulting in significant weight loss. Over weeks or months, the patient then develops symptoms of dementia including a slowing of thought processes and motor movements, incontinence, confusion, and in some cases, hallucinations and delusions. Initially, AIDS patients with dementia appear to be psychologically depressed with an observed reduction in normal emotional response, impaired memory, concentration problems, and social withdrawal. This can lead to seizures, mutism, and coma. In all probability, an encephalitis (inflamation of the brain) is involved, but the precise neuropathological mechanisms are not yet clearly understood. Since psychiatric response to AIDS and central nervous system dysfunction as a result of AIDS are so common, it is incumbent upon physicians to have AIDS patients routinely evaluated psychiatrically. Depression and suicide risk need to be assessed. Supportive psychotherapy, medication, or both, need to be provided. One must always keep in mind the potential for the central nervous system involvement and the development of dementia.

It is interesting to note that family support systems are beginning to develop in response to the catastrophic effects of AIDS on families, spouses, and significant others.[3]

Medical/Legal Issues

AIDS has presented medical specialists, psychiatrists included, dilemmas in terms of confidentiality. The American Psychiatric Association (APA) AIDS policy[4] indicates that physicians have an ethical obligation to guarantee privacy and confidentiality. If, however, the physician determines that the patient is continuing to put others at risk of infection, the APA feels it is ethically permissable for the physician to override confidentiality and notify those at risk. This is in accord with the psychiatrist's general duty to protect as defined in the *Tarasoff*[5] case[6]. The APA believes further that it is ethical for a psychiatrist to report to an appropriate public health agency the names of patients who are determined by convincing clinical information to be HIV infected (HIV positive means a person has been exposed to the Human Immune

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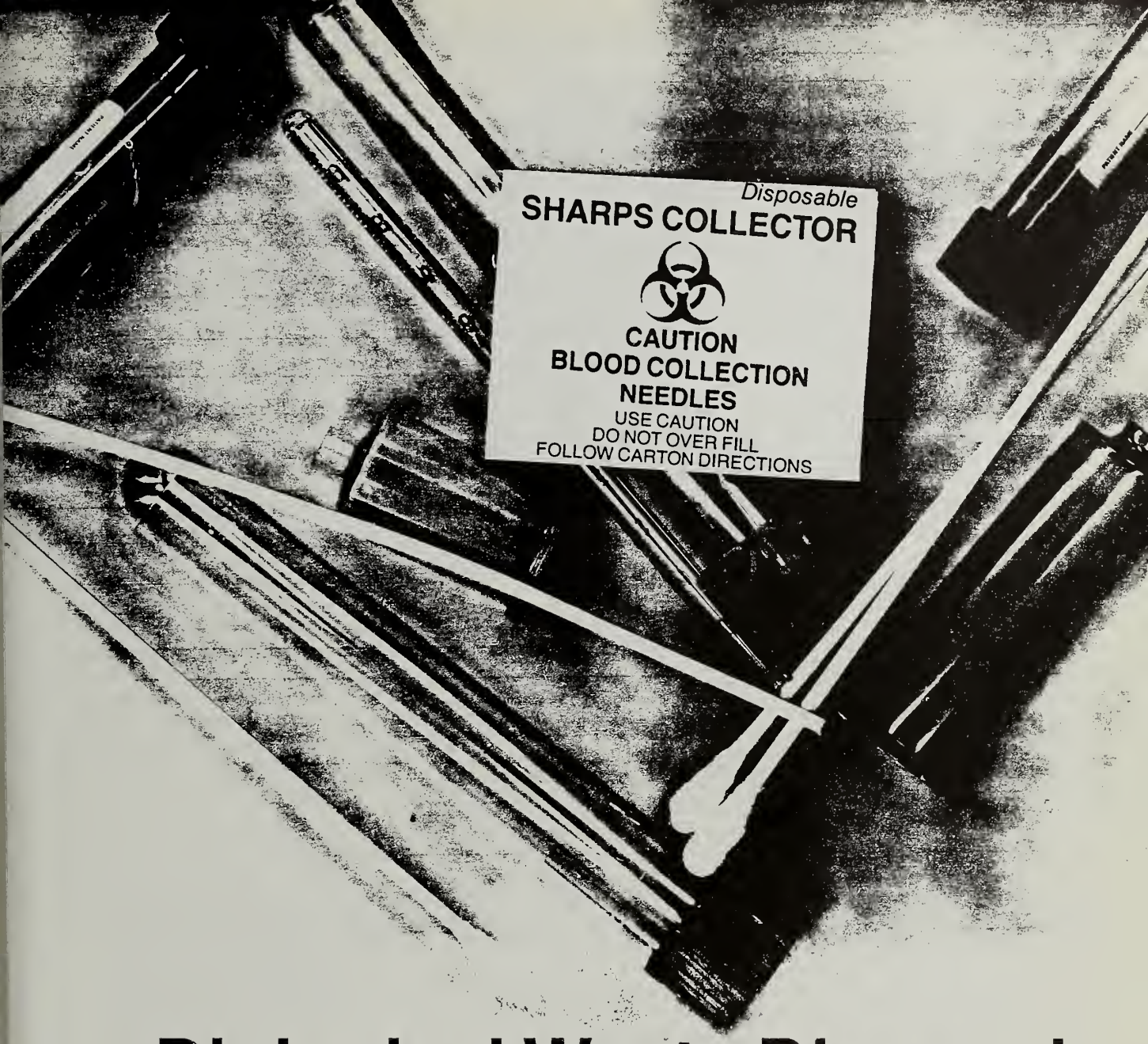

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Psychiatric and Psychological Aspects
(continued)

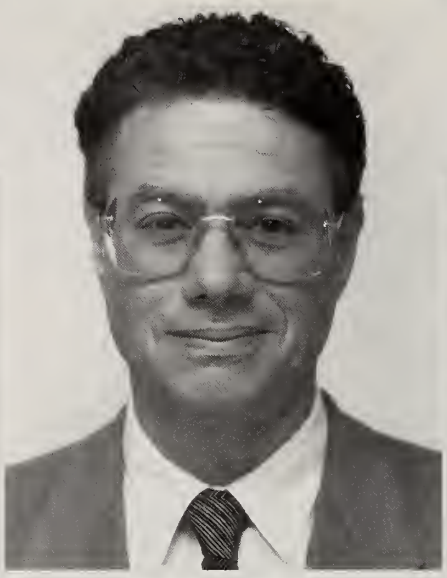
Deficiency Virus) and who the doctor feels are endangering others.

Demands for psychiatric hospitalization of HIV-positive persons, who engage in promiscuous activity or intravenous needle sharing may be expected.[7] Are such uses of commitment legitimate? Many facilities are unable to meet the medical needs of a symptomatic AIDS patient or even to protect their own patients from being infected by a promiscuous carrier. These questions and issues undoubtedly will be addressed in the next few years. ■

[1] Psychiatric Aspects of AIDS, by Faulstich, M., *American Journal of Psychiatry, 1987:* 144-551-6.

[2] Neuropsychiatric Aspects of Acquired Immune Deficiency Syndrome, by Loewenstein, R.J., and Sharfstein, S.S., *International Journal of Psychiatry and Medicine,* 1984: 13: 255-60.

[3] Support Group Helps Mothers Share Grief. Families of AIDS Patients Learn to Ease Pain, by Sari Straver, *American Medical News,* January 22/29, 1988; 3, 18-21.



[4] AIDS Policy: Confidentiality and Disclosure, *Psychiatric News,* January 15, 1988.

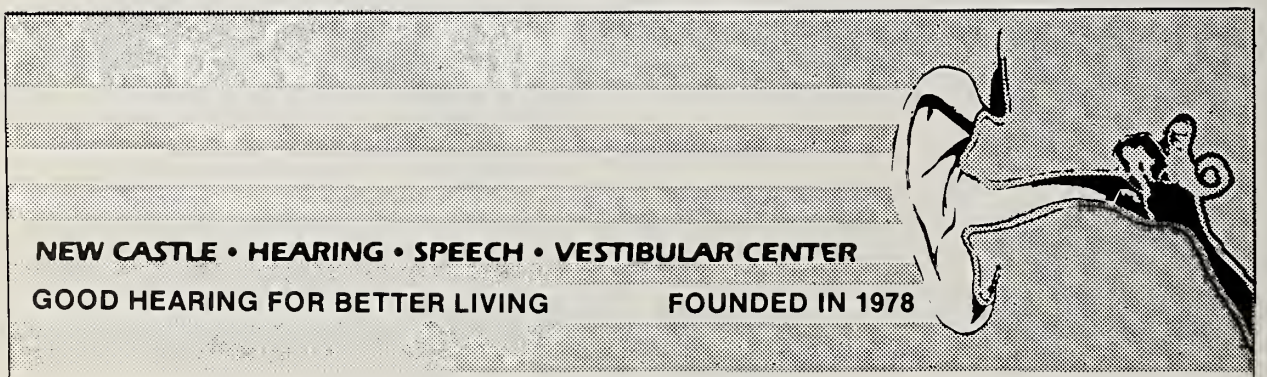
[5] *Tarasoff vs. Regents of University of California,* 131 Cal. Rptr. 14, 551 P2d 334 at page 347.

[6] Forensic Psychiatry and Psychology, Case Law Summary & Analysis Series, *Duty to Warn,* Joseph T. Smith, M.D., J.D., Steven B. Disbing, J.D., PsyD.

[7] AIDS, Psychiatry and the Law, by Paul S. Appelbaum, M.D., *Hospital & Community Psychiatry,* January, 1988; Vol. 39, No. 1, p. 13-14.

David Raskin, Chairman of the Department of Psychiatry at the Medical Center of Delaware, comes formidably well equipped to speak on the issues addressed in his accompanying article. He is not only an extremely distinguished psychiatrist; he has applied his skills to the examination and treatment of many patients suffering from AIDS.

To name but a few of his professional accomplishments, we note that he is Clinical Professor of the Department of Psychiatry and Human Behavior at Jefferson Medical College, in Philadelphia, and the Psychiatric Consultant for Correctional Facilities in Delaware. For the last sixteen years he has been an Examiner of the American Board of Psychiatry & Neurology. His many learned articles have appeared over the years in prominent medical and psychiatric journals. His recent initiative in combining medical and legal disciplines for the education of both professions in a continuing medical-legal education program, "The Insanity Defense", was enthusiastically received by doctors and lawyers alike.



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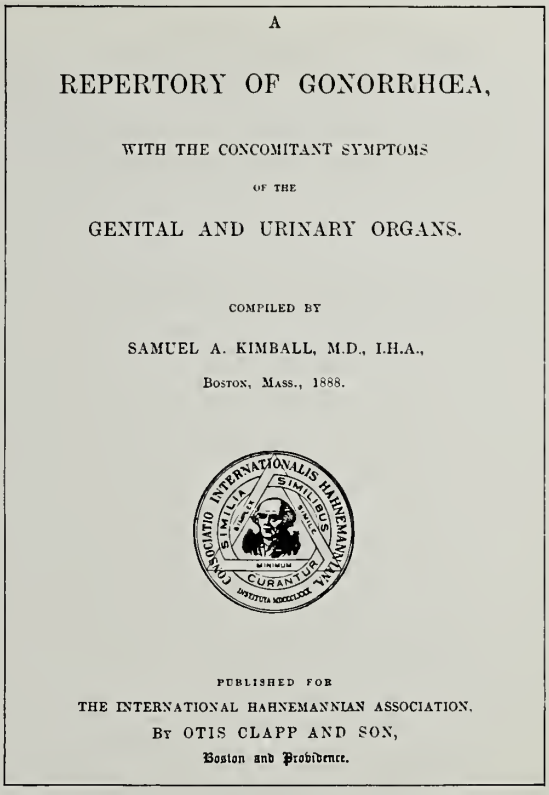
A

REPERTORY OF GONORRHŒA,

WITH THE CONCOMITANT SYMPTOMS

OF THE

GENITAL AND URINARY ORGANS.

COMPILED BY

SAMUEL A. KIMBALL, M.D., I.H.A.,

BOSTON, MASS., 1888.

PUBLISHED FOR

THE INTERNATIONAL HAHNEMANNIAN ASSOCIATION.

BY OTIS CLAPP AND SON,

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Sick through sin?

Mrs. Patrick Campbell, an English actress who flourished in the first quarter of this century, was at the height of her blunt powers of self-expression when an Edwardian sex scandal reduced London society to a state of lubricious hysteria. Mrs. Campbell dismissed the brouhaha with a civilized yawn: "Does it really matter what people do, so long as they don't do it in the streets and frighten the horses?"

The sentiment is decent. It endorses the right of privacy while upholding the claims of decorum. But it may become a dangerous sentiment to the extent that the notion of a right of privacy is pervertedly transformed into the power to kill by stealth. It is the purpose of this discussion not to urge the undermining of civil liberties, but to suggest a climate in which personal freedom and essential knowledge may coexist.

Behaving Badly Under Fire

For some years we have known that AIDS is a terrible threat to mankind. We have also learned that we should become fully informed about AIDS in its every aspect and that we should act decisively in accordance with that knowledge. Many, however, have been less interested in the pursuit of truth than in maintaining ideological purity. At the opposite ends of a political spectrum religionists of the far right and sexual minorities (and the officials who look to those very different constituencies for retention of office) have engaged in turfmanship and displays of indignation to the detriment of public health.

A few years ago I disposed of my father's medical library on the theory that several hundred out of date textbooks on urology had limited appeal for the general reader. I could not, however, resist saving a splendid oddity entitled "A Repertory of Gonorrhoea" by Samuel A. Kimball, M.D. (The principal charm of this otherwise useless volume — it was printed in 1888 — is the author's inspired choice of a publisher: the fine old Boston firm of Otis Clapp & Son.) Dipping into this peculiar treasure recently, I was startled by the durability of its Victorian point of view. The preface speaks of "the noble work of curing the sick, *"even if they are sick through sin."* (Italics supplied.) The same zest for moralistic responses to medical issues is in full flower today. All too frequently members of the religious far right equate AIDS with divine retribution. Although they speak perfunctorily about love and forgiveness, their core attitude towards the victims of AIDS appears to be patronization, laced with Old Testament wrath.

At the other end of that spectrum is politicized gayhood, which has suffered much to attain security in a lifestyle it now sees threatened by a linkage in public perception between AIDS and minority sexual preference. And, like the religious right, that minority is no stranger to folly in the defense of principle. In San Francisco, that Mecca of variegated love life, sensible public health measures intended largely for the protection of homosexuals have been angrily spurned by gay leaders as acts of covert homophobia. Apparently gays can be just as self destructively silly as their opponents.

Naturally this kind of doctrinaire wrongheadedness also prevails among the politically sensitive members of the United States Congress. It has been reported that the respected Henry Waxman, Chair of the House Subcommittee on Health and the Environment, has gotten into hell's own tangle in trying to craft useful AIDS legislation, beset by a fellow Committee member insistent upon making it plain that the United States government endorses neither homosexuality nor drug addition.

The misuse of the AIDS issue reached a new low in Chicago recently, according to the *New York Times* of Tuesday, July 26. A virulently antisemitic black activist, not surprisingly fired from the office of the Mayor, has declared "the AIDS epidemic is a result of doctors, especially Jewish ones, who inject AIDS into blacks". The *Times* account continues: this charmer now works for the Reverend Louis Farrakhan, who heartily endorses his allegations.

The Prudence of Concealment

In his article elsewhere in this issue Dr. Gerald Cioffi points out that it is "socially acceptable" to die of any of a number of afflictions, but *not* of AIDS, and Professor Furrow tells a cautionary horror story of a young man whose HIV positive diagnosis was leaked, costing him his job, his medical insurance, and his home.

The initial equation of AIDS and homosexuality has stirred up a frightening degree of hostility to gays, including violence to the point of murder. A decision of the United States Supreme Court has exacerbated this state of affairs by upholding statutory condemnation of minority sexual preference. *Bowers vs. Hardwick, et al,* 106 S. Ct. 2841 (1986). Instead of extending the *Griswold vs. Connecticut* right of privacy to all dis-

(Continued on next page)

creet consensual behavior (not in the streets and not frightening the horses) a majority of the Court embraced a traditionalist approach, stressing "crimes against nature" and the long history of the sodomy laws. *Bowers,* which does not even refer to AIDS, validates in half the jurisdictions in the Republic the criminalization of activity widely associated with AIDS. Concealment of infection thus becomes a sensible, if ignoble, course of conduct.

This is no place to examine *Bowers* as Constitutional adjudication. It is enough to recognize that this controversial decision of a sharply divided Court has not materially contributed to being open about a menace that cannot be confronted in the dark. Had Bowers gone the other way, declaring once and for all the right to conduct one's private life insulated from the censure of boudoir busybodies, our task would surely have been easier.

The Delaware Response

Seemingly resistant to the prejudices and pet lunacies described above, Delaware leadership in the AIDS crisis has been strong. At the April Professional Conference the Governor stated a continued resolve to deal with AIDS as a *medical* problem. The Attorney General has earned high marks for his handling of the Alfred I. duPont Institute dustup, and his office has kept itself remarkably well informed about the many legal developments in AIDS confronting us for the first time. (See David Lyons's article, *supra.*) But none of these encouraging signs should lull us into the belief that we in Delaware are immune to special interest digressions from effective response to the epidemic.

In September 1987 the AIDS Advisory Task Force of the Delaware Division of Public Health issued a lengthy report. It was later supplemented by a majority report on the issue of HIV testing, and a vigorous dissent from members of the medical community. Both appear in an appendix in this issue.

The Report, the work of a broad-based group of professional and community representatives, is an honorable achievement, distinguished by courteous deference to the prickly sensibilities of every imaginable concerned minority, racial or sexual. (Sometimes to bizarre effect: on page 11 the Report refers to "persons within the prostitution industry", a category that may raise a few eyebrows at the Chamber of Commerce.)

Perhaps the most significant features of the Report are a kind of muted hostility to HIV antibody testing and a gratuitous intrusion of sexual minority preachments.

"Because AIDS first affected the gay population in the United States, we have already seen lag time between the first manifestations of this disease and the recognition that we face a very serious public health problem. In other words, had the disease first struck the heterosexual community, the alarms might have been raised earlier, and more attention might have been given to education, research, and treatment." Task Force Report at page iii.

This is irrelevant to the problem at hand, which is to contain a plague. We should not be expending our energies on recriminations over the perceived inadequencies of our earlier response. But gay leaders, not unrepresented in the formulation of the Report, appear to demand simultaneously the glamour of martyrdom and the security of uncritical endorsement. Given the emotional climate surrounding AIDS, this deserves a good deal of sympathetic understanding. But the contamination by special interest agenda of Task Force deliberations has lead to a less than satisfactory piece of compromise legislation on HIV testing. See Lyons discussion at page 75.

Yes, even in enlightened Delaware* there is a pervasive tendency to put social priorities above sound medicine. At the Professional Conference in April Doctors Cioffi, Day, and Redfield argued eloquently for widespread and early HIV testing, not merely for the protection of the uninfected but for the provision of informed medical care to the infected at a time when they could still benefit from therapy. Their presentations of painful truths outraged several of those in attendance. One addressed a savage attack on Dr. Day to the authorities of the San Francisco Hospital where she practices and teaches orthopaedic surgery. (Shoot the messenger!) Another, learning of plans to show a videotape of the Conference to a group of policemen, persuaded the program moderator to dispense with the medical portion of the tape because it was "off the wall", which of course it most emphatically was not. It now appears that unpalatable truths are up against something uncomfortably close to prior restraint.

**The General Assembly has indeed acted responsibly. Handicap legislation (House Bill 135) is now law and should eliminate much discrimination against the infected.*

Giving Life a Chance

At the July symposium sponsored by the American College of Legal Medicine one speaker said it all in a few well chosen words. Here is an extremely accomplished doctor, Dr. Lonnie Bristow of the American Medical Association, telling lawyers and legislators what he as a medical specialist needs in stopping a plague:

"Discrimination triggered by the fear of AIDS may increase the risk of the spread of AIDS because those at risk may not come forward for testing and counseling. Therefore, discrimination threatens not only those who are infected, but the rest of society as well."

Consider the source of these wise words. This is not gay propaganda. This is not the extravagance of a hypersensitive civil libertarian. It is the informed assessment of one qualified to deal with a problem that is above all else a medical one. It appears that doctors and lawyers have united in fostering this emergence of dazzling common sense. Former President Robert MacCrate of the American Bar Association has spoken out strongly against discrimination as it bears on the AIDS crisis.

What are the prospects for common sense triumphant? Well, in the long run, when things get bad enough, common sense has a wonderful way of reasserting itself in the face of ideology and prejudice. The Task Force Minority Report on the issue of HIV testing correctly asserts that the time has come to stigmatize the discriminators instead of the sufferers. Despite (or perhaps because of) the shadows cast by *Bowers vs. Hardwick,* we need to adopt the most stringent antidiscriminatory measures. Those at risk must feel safe in informing themselves and, if infected, in pursuing competent medical help.

I am confident in the triumph of sanity. It will not be the first occasion that our free society has shown the strength to abandon preconceptions in order to grapple with unpleasant truths and to succeed in so doing. ■

William E. Wiggin

Informed Consent and Confidentiality Regarding HIV Related Tests

(Final informed consent/confidentiality legislative recommendations from State's AIDS Advisory Task Force)

Section 1. Definitions

1. **AIDS** - Acquired Immunodeficiency Syndrome

2. **HIV** - the human immunodeficiency virus identified as the causative agent of AIDS.

3. **HIV related test** - a test for the antibody or antigen to HIV.

4. **Health facility** - a hospital, nursing home, clinic, blood bank, blood center, sperm bank, laboratory, or other health care institution.

5. **Health care provider** - any nurse, physician, dentist and other dental worker, optometrist, podiatrist, chiropractor, laboratory and blood bank technologist and technician, phlebotomist, dialysis personnel, emergency health care provider (including any paramedic, emergency medical technician, law enforcement personnel, or firefighter), and others whose activities involve contact with patients, their blood or corpses.

6. **Legal guardian** - a person appointed by a court to assume legal authority for another who has been found incompetent or, in the case of a minor, a person who has legal custody of the child.

7. **Person** - any natural person, partnership, association, joint venture, trust, public or private corporation, or health facility.

8. **Release of test results** - a written authorization for disclosure of HIV related test results which is signed, dated and which specifies to whom disclosure is authorized and the time period during which the release is to be effective.

Section 2. Informed consent.

A. No health facility, health care provider, or other person shall test or shall cause by any means to have tested, any specimen of any patient for HIV related tests, without the informed consent of the subject of the test or the subject's legal guardian. A health care provider shall ensure that informed consent has been received prior to ordering testing by a laboratory or other facility.

B. Informed consent to an HIV related test shall consist of a voluntary agreement executed by the subject of the test or the subject's legal guardian. If the agreement is oral, the facts pertaining thereto must be documented by customary practice. Informed consent shall consist of at least the following:

(1) an explanation of the test, including its purpose, potential uses, limitations, and the meaning of its results;

(2) an explanation of the procedures to be followed, including that the test is voluntary, that consent may be withdrawn, and the extent and limitations of the manner in which the results will be confidential;

(3) an explanation of the nature of AIDS and other manifestations of HIV infection and the relationship between the test result and those diseases; and

(4) information about behaviors known to pose risks for transmission of HIV infection.

C. Notwithstanding Section 2A, the provisions of Sections 2A and 2B do not apply when

(1) knowledge of such test results are necessary for medical diagnostic purposes to provide appropriate emergency care or treatment and the subject of the test is unable to grant or withhold consent;

(2) the testing is done for the purposes of research, provided that the test is performed in a manner by which the identity of the test subject is not known and may not be retrieved by the researcher.

(3) a health care provider or health care facility procures, processes, distributes or uses (i) blood, (ii) a human body part donated for a purpose specified under the Uniform Anatomical Gift Act, or (iii) semen provided prior to the effective date of this Act for the purpose of artificial insemination, and such test is necessary to assure the medical acceptability of such gift or semen for the purposes intended.

(4) necessary to control the transmission of HIV infection as may be allowed pursuant to 16 Del. C. Chapter 7 et. seq. as it relates to sexually transmitted diseases, or 11 Del. C. Section 6523 (b) as it relates to the Department of Corrections.

(5) testing is ordered by a court of competent jurisdiction within the confines of civil or criminal litigation where the results of an HIV related test of a party, or a person in the custody or under the legal control of another party, is relevant to the ultimate issue of culpability and/or liability. Said order shall be issued in compliance with the following provisions:

(i) No court of this State shall issue such order unless the court finds that there is a compelling need for such test results which cannot be accommodated by other means. In assessing compelling need, the court shall weigh the need for testing and disclosure of the test results against the privacy interest of the test subject and the public interest which may be disserved by disclosure which deters future testing or which may lead to discrimination.

(ii) Pleadings pertaining to ordering of an HIV related test shall substitute a pseudonym for the true name of the subject of the test. The true name shall be communicated confidentially, in documents not filed with the court.

(iii) Before granting any such order, the court shall provide the individual whose test result is in question with notice and a reasonable opportunity to participate in the proceedings if he or she is not already a party.

(iv) Court proceedings as to disclosure of test results so ordered shall be conducted *in camera* unless the subject of the test agrees to a hearing in open court or unless the court determines that a public hearing is necessary to the public interest and the proper administration of justice.

D. Any person on whom an HIV related test was performed without first having obtained informed consent pursuant to Section 2C(1), 2C(4) and 2C(5) shall be given notice promptly, personally and confidentially that a test sample was taken and the results of such test may be obtained upon request.

E. At the time of learning the test result, the subject of the test or the subject's legal guardian shall be provided with counseling for coping with the emo-

(Continued on next page)

tional consequences of learning the result, for understanding the interpretation of the test result, for understanding measures for preventing infection to others, and to urge the voluntary notification of sexual and needle sharing partners of the risk of infection.

F. Notwithstanding any other provision of law, a minor 12 years of age or older may consent or refuse consent to be a subject of HIV related testing and to counseling relevant to the test. The consent or refusal of the minor shall be valid and binding as if the minor had achieved his or her majority, and shall not be voidable, nor subject to later disaffirmance, because of minority.

Section 3. Confidentiality.

A. No person may disclose or be compelled to disclose the identity of any person upon whom an HIV related test is performed, or the results of such test in a manner which permits identification of the subject of the test, except to the following persons:

(1) The subject of the test or the subject's legal guardian.

(2) Any person who secures a legally effective release of test results executed by the subject of the test or the subject's legal guardian.

(3) An authorized agent or employee of a health facility or health care provider if the health facility or health care provider itself is authorized to obtain the test results, the agent or employee provides patient care or handles or processes specimens of body fluids or tissues, and the agent or employee has a medical need to know such information to provide health care to the patient.

(4) Health care providers providing medical care to the subject of the test, when knowledge of the test results is necessary to provide appropriate emergency care or treatment.

(5) When part of official report to the Division of Public Health as may be required by regulation.

(6) A health facility or health care provider which procures, processes, distributes or uses: (i) blood, (ii) a human body part from a deceased person donated for a purpose specified under the Uniform Anatomical Gift Act; or (iii) semen provided prior to the effective date of this Act for the purpose of artificial insemination.

(7) Health facility staff committees or accreditation or oversight review organizations which are conducting program monitoring, program evaluation or service reviews.

(8) Pursuant to 16 Del. C. Section 901 et. seq. as it relates to investigation of child abuse.

(9) Pursuant to 16 Del. C. Section 7 et. seq. as it relates to sexually transmitted diseases and their control.

(10) A person allowed access to said record by a court order which is issued in compliance with the following provisions:

(i) No court of this State shall issue such order unless the court finds that the person seeking the test results has demonstrated a compelling need for the test results which cannot be accommodated by other means. In assessing compelling need, the court shall weigh the need for disclosure against the privacy interest of the test subject and the public interest which may be disserved by disclosure which deters future testing or which may lead to discrimination.

(ii) Pleadings pertaining to disclosure of test results shall substitute a pseudonym for the true name of the subject of the test. The disclosure to the parties of the subject's true name shall be communicated confidentially, in documents not filed with the court.

(iii) Before granting any such order, the court shall provide the individual whose test result is in question with notice and a reasonable opportunity to participate in the proceedings if he or she is not already a party.

(iv) Court proceedings as to disclosure of test results shall be conducted *in camera* unless the subject of the test agrees to a hearing in open court or unless the court determines that a public hearing is necessary to the public interest and the proper administration of justice.

(v) Upon the issuance of an order to disclose test results, the court shall impose appropriate safeguards against unauthorized disclosure, which shall specify the persons who may have access to the information, the purposes for which the information shall be used, and appropriate prohibitions on future disclosures.

B. No person to whom the results of an HIV related test have been disclosed pursuant to Section 3A may disclose the test results to another person except as authorized by Section 3A.

C. The provisions in this section shall not interfere with the transmission of information as may be necessary to obtain third-party payment for medical care related to HIV infection or with the documentation of cause of death on death certificates.

Section 4. Remedies and Penalties.

A. Intentional or reckless violations of Sections 2 or 3 shall constitute a misdemeanor.

B. Any person aggrieved by a violation of this Act shall have a right of action in the Superior Court and may recover for each violation:

(1) Against any person who negligently violates a provision of this Act, liquidated damages of $_____ or actual damages, whichever is greater.

(2) Against any person who intentionally or recklessly violates a provision of this Act, liquidated damages of $_____ or actual damages, whichever is greater.

(3) Reasonable attorney fee.

(4) Such other relief, including an injunction, as the court may deem appropriate.

(5) Any action under this Act is barred unless the action is commenced within three years after the cause of action accrues. A cause of action will accrue when the injured party becomes aware of an unauthorized disclosure pursuant to Section 3, or that an HIV related test has been conducted without informed consent pursuant to Section 2.

C. When considering the state of mind of a person alleged to have violated a provision of this Act, reference shall be had to 11 Del. C. Section 231 which specifies definitions relating to state of mind.

D. The Attorney General may maintain a civil action to enforce this Act in which the court may order any relief authorized by Section 4B.

E. Nothing in this Act shall be construed to impose civil liability or criminal sanction for disclosure of an HIV related test result in accordance with any reporting requirement by the Division of Public Health.

(See page 81 for Minority Report)

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A Commitment to Hope
Intellect, Capital, and Social Responsibility

John F. Maguire

The importance of the resources of private enterprise in the war against disease is insufficiently recognized, but in the case of AIDS they may turn out to be dispositive. Tracking the virus and confronting it is capital intensive business. To Delawareans it should be of particular interest that the DuPont Company, the state's chief employer and largest chemical manufacturer, has a major commitment to health science.

John F. Maguire, the Sales and Marketing Manager, North America/South America of the DuPont Medical Products Department, spoke at the Professional Conference, describing the DuPont initiative. The following is drawn from his remarks.

I would like to thank the Delaware State Bar Association, the Delaware State Dental Society and the Medical Society of Delaware for giving me a chance to share with you a little of what DuPont has been doing in the area of AIDS.

As of March, 1988, more than 53,000 Americans have been diagnosed with AIDS. Nearly 12,000 of these are under age 30. More than 20,000 of these have already died of AIDS. It is estimated that 1.5 million Americans carry the virus. The latest information is that 75 percent of them will develop the disease within six years of infection. The Surgeon General estimates that in just three more years, there will be 270,000 cases of AIDS in the U.S., with 179,000 deaths. The cost of providing healthcare to the people afflicted with AIDS will be between 8 billion and 16 billion dollars by 1991.

As I see it there are five major concerns with AIDS. They are 1) Understanding and preventing the methods of transmission, 2) Developing ways to detect and diagnose infection and disease, 3) Providing health care professionals with ways to counsel and monitor infected persons, 4) Developing a treatment or cure for people with AIDS, and 5) Finding a way to prevent the disease. The DuPont Company is active in each of these efforts.

Understanding and Preventing Methods of Transmission

It became clear in 1984, after the cause of AIDS was discovered by Doctors Robert Gallo at the National Cancer Institute and Luc Montagnier at the Pasteur Institute, that AIDS was being spread in three primary ways—through direct contact with contaminated blood and blood products, through sexual contact with infected persons, and from infected mother to newborn infant. To prevent transmission the first thing needed was a test to detect the presence of AIDS contaminated blood. DuPont, working with our partner, Biotech Research Laboratories, was one of five companies to be granted a license by the government to develop and commercialize a test that could detect the presence of antibodies to the human immunodeficiency virus. We received approval to market such a test late in 1985. These screening tests were designed for one major purpose—to make certain AIDS contaminated blood would be kept out of the nation's blood supply. About 1200 people to date have been diagnosed with AIDS as a result of receiving transfused blood containing the AIDS virus. However, since testing of all donated blood began in 1985, we have effectively controlled blood transfusions as a method of transmission. Today, the DuPont HIV screening test is being used at blood centers around the world. This success is the result of providing our customers with a test that worked extremely well, and then supporting them with systems and procedures to help provide their communities with safe blood.

While the purpose of these screening tests was to keep the blood safe, it was clear very early on that these tests were also being used to test people. Since the purpose of the tests was to eliminate transmission of the disease through transfusion, they were intentionally designed to be highly sensitive, as to preclude false negative results. However, to achieve this high level of sensitivity, the tests can result in false positives. From a blood safety standpoint that really doesn't matter, because if there is any indication that the blood is contaminated, it is discarded. However, it is not acceptable to notify people that they might be infected when they are not. To deal with that, DuPont and Biotech Research Labs

have developed another kind of test called the Western Blot. This product addresses the second concern—*Developing ways to detect and assist in the diagnosis of HIV infected people.* While the diagnosis of AIDS is a clinical procedure, involving the manifestation of symptoms such as Pneumocystis Pneumonia, the beginning of that process is to determine that one has developed antibodies to the AIDS virus. Once a person has been found to be antibody positive by the screening test a Western Blot test is run. The results of a Western Blot are not only more definitive, but they are also more descriptive. Instead of yielding a mere yes or no to the presence of antibodies to the AIDS virus, which is the information gained from a screening test, the Western Blot gives specific information about the individual antibodies and their quantity, which are directed against the various parts of the structure of the virus. To date, the Biotech/DuPont Western Blot kit is the first and only confirmatory test that has been licensed by the FDA.

The Western Blot can also address the third concern—*providing physicians with better information to counsel and monitor infected individuals.* The Western Blot is not only useful in confirming the presence of infection; it may well be helpful in predicting when a healthy person who has antibodies to the AIDS virus, may develop symptoms of disease.

Another product developed by DuPont which can be used to determine the stage of disease and effectiveness of therapy is the P24 Core Antigen test. This test is capable of detecting the presence of the AIDS virus itself rather than antibodies to the virus. Researchers are now using this test to watch what is happening to those who are healthy but antibody positive. The Western Blot shows the level and kind of *antibodies*, the Antigen tests the level of *virus.* The predictive value of these tests derives from their capacity to monitor the decreasing amount of antibodies and the corresponding increasing amounts of virus.

Other tests under development at DuPont include a genetically engineered or recombinant test that is manufactured without using any live virus. This test is not only safer to manufacture, it appears to be even more sensitive and specific than the existing virus based screening tests. We are currently selling this new test in Europe. We are also in the process of evaluating a rapid, visual, manual test for AIDS antibodies. Called Hivchek, this matchbook size test is designed to be used without laboratory equipment, can withstand extreme climate conditions, and doesn't require highly skilled technicians. We believe this kind of test will be particularly useful for developing nations, especially those in Central Africa where AIDS is still being transmitted through blood transfusions. We are also developing a screening test for a new variety of the AIDS virus, called HIV-2. While HIV-2 is not believed to be present in the United States, if and when it arrives, we hope to be ready with a screening test.

(Continued on next page)

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Commitment to Hope
(continued)

DuPont has also developed a screening test for another retrovirus—HTLV-1. While not nearly as well known as HIV, this virus has a lot of similarities to the AIDS virus. This virus can be spread the same way as AIDS, and can lead to serious disease, such as adult T-cell Leukemia, and ultimately death. We expect the FDA to license our HTLV-1 antibody test this year, and for blood centers to begin screening for HTLV-1 antibodies soon thereafter.

Our next concern is *developing ways to treat or cure AIDS.* Last year DuPont entered into an agreement with H.E.M. Research of Rockville, Maryland, which had developed a drug called Ampligen. Initially, it was thought Ampligen might be effective in treating certain kinds of cancer. An early clinical trial in England showed reason to hope that Ampligen might well be effective in treating people with ARC (AIDS Related Complex), which at this time is its only indication. DuPont and H.E.M. joined forces earlier this year, and today expanded clinical trials are underway at six different hospitals in the U.S. including Hanneman, to determine if Ampligen will be effective in treating ARC. While we do not expect definitive results for another few months, we are hopeful that Ampligen may well be an effective treatment for ARC patients. If clinical trials progress at the current rate, we expect availability in late '88 or early '89.

Finding Ways to Prevent the Disease

Although DuPont is not directly involved in developing a vaccine for AIDS, the company is contributing to research. Before an effective vaccine can be developed, we will need to increase our understanding of the virus and the way it works. It may surprise many to learn that the AIDS virus was first sequenced right here in Delaware at the DuPont Experimental Station. The unraveling of the genetic code of HIV took a team of DuPont researchers, working with Dr. Robert Gallo at The National Cancer Institute, nearly a year. Earlier this year DuPont introduced an automated DNA sequencing system, called the Genesis 2000, that could have done the job in about a week. Since that initial effort to sequence the AIDS virus,

our researchers have continued work to build on the growing body of knowledge necessary to the development of an effective vaccine.

Finally, DuPont is committed to supporting the research community at large with products designed to assist basic AIDS reasearch. I don't know of any other company that offers researchers the range and depth of products to unravel the AIDS mystery. In all, we have available some 40 different research products being used by AIDS reserachers around the world. These include such sophisticated products as DNA or RNA probes, monoclonal antibodies, a new centrifuge that is particularly useful in viral research, and much more.

DuPont is very serious in its efforts to contribute to improved health care. In 1987 the corporation spent about a quarter of a billion dollars in health care research. Those monies are being invested in finding ways to diagnose or treat such diseases as cancer, heart disease, arthritis, Altzheimer's Disease, and others. However, a significant portion of these efforts and financial resources during 1987 and the past five years have been devoted to AIDS. We have every reason to believe the kind of commitment we made in materials research 50 years ago that led to Nylon and Teflon will produce equally important contributions in solving the AIDS crisis as well as in health care in general.

AIDS is a disease that people can learn to avoid. While we must continue to find better ways to detect and treat this disease, we must also help people to understand what they can do to protect themselves and their loved ones. To that end, we have prepared and are making widely available a pamphlet titled "Understanding AIDS." This pamphlet is not only available to DuPont personnel but to the general public. There is a toll free number, 800-441-7515 that anyone can call to get this pamphlet.

I look forward to the day when we can all meet together again, and look at what those of us in industry, government, and the medical community have done together to beat AIDS. ■

John F. McGuire, a graduate of Harvard with degrees in Chemistry and Business Administration, held positions in Products and Marketing with New England Nuclear Corp. of Boston, Massachusetts. When DuPont acquired New England Nuclear, he became National Sales Manager of the Specialty Diagnostics Division of the DuPont Medical Products Department. Today he is the Sales and Marketing Manager, North America/South America of that Division. Mr. McGuire's remarks were delivered at the Professional Conference on AIDS.

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AIDS: Designing a Balanced Legislative Response

Barry Ray Furrow

AIDS is a medical problem, a legal problem, a public health problem—but it is first of all an individual's problem. No professional specialty can lay sole claim to the territory. Professional collaboration is essential. Lawyers, doctors and scientists must forge a close working relationship in coping with AIDS. Just as lawyers must learn to think in terms of rates of testing error, clinical trials, and disease vectors, so physicians and scientists need to become familiar with the power of the law and its limits. Just as we have not found a medical magic bullet for AIDS, so we do not have a legal tool that enforces behavior modification overnight.

Law, policy, science and medicine blend in the crucible of AIDS-generated responses. In the face of scientific uncertainty, legal responses piggyback on medical knowledge and epidemiological discovery. Precipitous legal reactions are dangerous until we better understand the risks of the disease, its scope, and the limits of our ability to test for it and treat it.

I. The Temptations.

A. The temptation for non lawyers and legislators, and for lawyers as well, is to view the law as a weapon in a Clint Eastwood movie. We pass a law, we act, and the problem is eliminated. The easy fix, invoking the ready arsenal of legal tools, is tempting to the legislator. It is never that easy, and with AIDS even less so.

B. The temptation has been to view the AIDS problem as largely limited to a stigmatized minority. But it is rapidly becoming a heterosexual problem. As of February 1987, 30,000 Americans have been diagnosed as having AIDS. Perhaps five to ten times that number have AIDS related complex (ARC). The Public Health Service estimates that 270,000 Americans will develop AIDS by 1991. Since this projection is based on the number already infected with HIV, it does not take into account those likely to be infected in the future. 73% of those diagnosed with AIDS have been gay men, and this has fostered a backlash in the form of discrimination and violence. Sexual practices in the general population will now endanger increasing numbers of heterosexuals.

C. The temptation to overreact is likely, ironically, as we acknowledge that the AIDS problem now transcends sexual orientation. People's careers and rights may be unfairly impaired. As Benjamin Schatz of the AIDS Civil Rights Project has written:

People who have or are perceived to be at risk for AIDS have been fired from their jobs, evicted from their homes, refused services by businesses and government agencies, and denied visitation provileges with their children. Doctors have been evicted from their offices for treating people with AIDS, while other medical personnel have refused to offer treatment. Discrimination may persist even after death; some funeral homes have refused to accommodate the bodies of people who have died from the disease. Schatz, "The AIDS Insurance Crisis: Underwriting or Overreaching?", 100 *Harv. L. Rev.* 1782, 1784 (1987).

D. The temptation exists to use available and important tools such as the ELISA test overzealously in the misplaced optimism that such tests are more accurate than in fact they are in pinpointing the locus and magnitude of the problem in all potentially affected population groups. Standardization in testing is a problem, as is the error rate in smaller laboratories with less skilled technicians. Variation among laboratories in test characteristics can lead to unacceptably high false positive test results.

See Meyer and Pauker, "Screening for HIV: Can We Afford the False Positive Rate?" 317 *N. Eng. J. Med.* 238 (1987) ("hasty and indiscriminate screening for antibody to HIV is imprudent and potentially dangerous . . ."); Barry, Cleary, and Fineberg, "Screening for HIV Infection: Risks, Benefits and the

(Continued on next page)

Barry Ray Furrow, a graduate of Harvard College and Harvard Law School, is a professor at the Widener University School of Law, Delaware Campus. He was previously a professor at the University of Detroit School of Law and the Director of the Health Law Center at that University. He has taught and written extensively on health law, law and medicine, and law and science. Professor Furrow was one of the speakers at the Professional Conference on AIDS.

Burden of Proof," 14 *Law, Medicine & Health Care* 259 (1987) (burden of proof on necessity for HIV screening should rest with those proposing to test).

We live in an imperfect world, in which confidences are often violated, employees retaliate, acquaintances shun, landlords evict. We are all afraid of AIDS and the possibility of our exposure to it. For many of us, its current prevalence in populations that we may find unattractive—gays, drug users—makes the disease even more socially uncomfortable. As a result, the act of testing for AIDS carries significant risks for the person tested. Tests can have adverse consequences even if the result is accurate; if the result is incorrect, the consequences can be truly destructive. Let me quote an example from a recent article in the *Journal of the American Medical Association,* written by a physician:

In 1985, I was the primary physician for a young man whose life was ruined by the inappropriate disclosure of a positive human immunodeficiency virus (HIV)-antibody test. A physician ordered the test without consent and notified the local health department of the positive result. The health department notified the individual's employer and he was promptly fired. These events became common knowledge at his workplace and in his rural Midwestern town and he was shunned. His landlord asked him to move. Ten days after testing, the life he had known for the past ten years was permanently ruined and he left town. With the loss of his job came loss of health insurance and insurability; he has been unable to obtain health or life insurance since then. (JAMA, Jan. 8, 1988—Vol 259, No. 2)

This defines the outer limits of risk in careless or inaccurate HIV testing—loss of job; uninsurability; shunning; adverse psychological consequences, including suicide attempts and major depressive illness; and a false sense of security with a negative result.

II. The Legal Dimensions.

The law is a mechanism for handling and allocating risks—of economic and personal loss, injury, future harm to self and others—and for facilitating individual and social goals, in an attempt to accommodate, or at least provide a forum for settling, often clashing interests. It is also a source of norms for social conduct, backed by the ability of courts and legislatures to articulate these norms through judicial opinions and through legislation.

A. Public health efforts. State legislatures are pumping out the legislation, and Congress is considering hundreds of bills. The goal of all of these efforts is to better understand the epidemic, to modify risky behavior, and to provide treatment for those afflicted.

The public health functions of a legal response can be grouped into six categories.

1. Planning Strategies. Task forces are established and guidelines published to recommend strategies and precautions for slowing the spread of AIDS. The State of Delaware has created such a Task Force, which is to be commended for its careful work on proposals for legislation to deal with

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2. Informing Choice. Public health officials can be authorized or required to provide the general public or specific groups with services: education, counseling, and social support. The private counterpart is in the hands of physicians and therapists: they must understand with precision what is known about the risks of contagion of AIDS, its mechanisms and epidemiology, and tell patients where they stand and what options they have. We don't want to repeat the mistakes we made in the past in handling diseases such as syphilis.

See, e.g., Brandt, "AIDS: From Social History to Social Policy," 14 *Law, Medicine & Health Care* 231 (1987)

Accurate information is needed, transmitted not only in the privacy of the medical suite, but also through the mass media in explicit terms, not in the euphemisms of "bodily fluids" mysteriously transmitted through unspeakable orifices.

Accurate information is needed, transmitted not only in the privacy of the medical suite, but also through the mass media in explicit terms, not in the euphemisms of "bodily fluids" mysteriously transmitted through unspeakable orifices.

3. Regulating to Control. Legislatures have considered mandating compulsion against individuals via such regulatory functions as case finding (screening, reporting, and contact tracing), segregation of prisoners, exclusion of infected individuals from school or certain professions, isolation of persons with AIDS, imposition of criminal penalties for intentional sexual transmissions; or regulation of meeting places such as bathhouses. Some or all of these legislative choices may be unconstitutional; many pose significant dangers to civil liberties and individual autonomy.

The public health perspective blends epidemiology and medicine with education and state action. Public health looks at the role of the state in fostering health by prevention, education, and isolation. But the traditional public health tools do not fit well with this new disease. See Parmet, "AIDS and Quarantine: The Revival of An Archaic Doctrine," 14 *Hofstra L. Rev.* 53 (1985); Curran, Clark, and Gostin, "AIDS: Legal and Policy Implications of the Application of Traditional Disease Control Measures," 14 *Law, Medicine & Health Care* 27 (1987).

Public health broadly defined also includes a range of government regulation through administrative agencies that have a direct impact on AIDS research, testing, funding and treatment. Consider Food and Drug Administration policies on drug research and human experimentation; National Institutes of Health policies on research; Occupational Health and Safety Administration regulation of workplace safety; Federal Trade Commission advertising policy, as it becomes clear that marketing of condoms and safety information generally could be effectively done through radio and television. The government is already heavily involved, but its involvement has too often been largely fragmented and uncoordinated.

4. Regulating to Protect. Courts and state legislatures have a major role to play in safeguarding the rights of those who test positive, those with ARC, and with AIDS. These individuals must be protected by ensuring their privacy and the confidentiality of health care information and prohibiting discrimination in employment, housing, and insurance. AIDS presents the law with a strong tension: between individual rights and a State desire to protect the uninfected public. Given the inevitable error rates as testing volume increases beyond the best laboratories, and the nature of the AIDS virus (in the words of infectious disease experts, a "wimpy" virus), the burden of proving the need for onerous and personally dangerous regulation lies with its proponents.

AIDS presents the law with a strong tension: between individual rights and a State desire to protect the uninfected public.

5. Facilitating Treatment. The law can facilitate treatment in a variety of ways.

a. Remove disincentives to prevention and treatment. How does the law provide incentives for research on vaccines, and how is the law counterproductive? Manufacturers are worried about their tort exposure if a vaccine is

(Continued on page 55)

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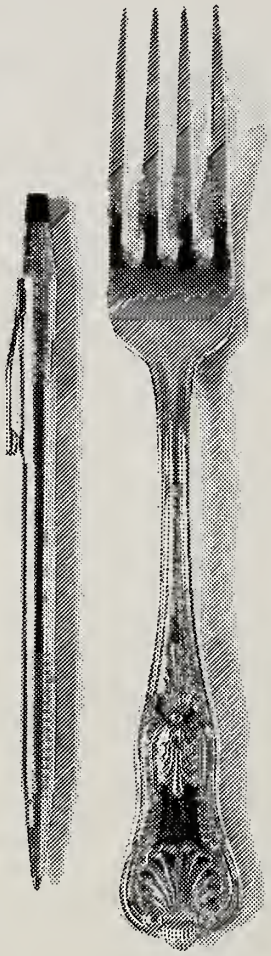

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Legislative Response
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developed that has pernicious side-effects. See Mariner and Gallo, "Getting to Market: The Scientific and Legal Climate for Developing an AIDS Vaccine," 15 *Law, Medicine & Health Care* 17 (1987) (discussing problems with buffering vaccine manufacturers against liability for side effects of vaccines).

b. Develop mechanisms and new institutional forms for funding and locating treatment. How is treatment for those with AIDS funded? What federal and state policies should be adopted to pay for this new catastrophic illness? What modes of institutional treatment should be available? Should we design and fund a new hospice program with heavy subsidies and incentives to provide humane and economical cost for the dying? See Bulkin and Lukashok, "Rx for Dying: The Case for Hospice," 318 *N. Eng. J. Med.* 376 (1988); Report of the Commission.

The financing perspective forces us to consider both governmental and private mechanisms for insuring the AIDS patient, from the point of view of state risk pools, private insurance, and national handling of AIDS treatment through existing and expanded programs such as Medicare and Medicaid. We handle our life insurance through private insurance, and our health insurance through a complex mixture of federal programs like Medicare and private insurance like Blue Cross and other third party insurers. AIDS poses an actuarial nightmare for the insurance industry, and they are struggling to avoid insuring a person who is likely to fall into a high risk category for exposure to the disease. But should they be allowed to avoid insuring this risk pool? Isn't the value of insurance precisely its spreading of social risks over a large pool of insureds?

See Clifford and Iuculano, "AIDS and Insurance: The Rationale for AIDS-Related Testing," 100 *Harv. L. Rev.* 1806 (1987) (arguing for proposition that insurers must be allowed to use AIDS-related testing to determine insurability, in order to avoid distorting the fair and equitable functioning of the insurance pricing system); contra, Schatz, "The AIDS Insurance Crisis: Underwriting or Overreaching?", 100 *Harv. L. Rev.* 1872 (1987) (financial concerns of the insurance industry insufficient to outweigh the social, medical, and moral costs of sexual orientation discrimination or HIV antibody testing.)

6. *Facilitating Death.* Lawyers spend substantial portions of their time in private practice preparing clients and their families for death, by drafting wills, trusts and estate plans. New tools have been added to cope with medical decisionmaking and incompetent patients: living wills, durable powers of attorney. AIDS patients at the end of their disease trajectory have need of these legal instruments as well as the more traditional ones. Until we have managed either to prevent the disease or to offer a cure, the magic bullet will have to be replaced by the half best legal document.

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Legislative Response
(continued)

negligence. The threat of a tort suit frightens and angers medical professionals, and simply frightens laymen. AIDS promises a new spectrum of tort actions for grievous injury to others: the doctor who fails to recognize the symptoms and properly advise a patient, thereby turning him loose to infect others unknowingly; the individual who gives AIDS to his or her lover knowing that his disease is well developed; the testing laboratory that sloppily conducts a test and produces a deceptive false negative rate. What must the extent of informed disclosure be? To what extent must that doctor shoulder the obligations of warning a third party about a patient's level of antibodies? His ARC status? His AIDS status? Tort law provides some hints as to the directions the courts may take in this area.

The problem with a tort suit is that it is at best an indirect and limited method of deterring people from engaging in negligent or intentional risky conduct. And it is also primarily a compensation mechanism. With AIDS, we need to develop more efficient means of transferring resources to the afflicted for their care than the tort mechanism can systematically provide. Nonetheless, the threat of a tort suit for a variety of AIDS-related acts of negligence and intentional misconduct is desirable to insure a minimal level of cautious behavior.

C. Criminal actions to punish. Several criminal actions have been brought against individuals for knowingly or recklessly transmitting or intending to transmit the AIDS virus. Should we criminalize AIDS, so that mere refusal to be tested is criminal? So that intentional or reckless exposure of another to the virus is a crime? These are difficult questions that address the nature and power of the legal system, and its limits.

See Field, and Sullivan, "AIDs and the Criminal Law," 15 *Law, Medicine & Health Care* 46 (1987) (concluding that an AIDS-specific criminal statute is not a desirable means of fighting the spread of AIDS, because of fears of harassment of select groups and deterrence of their seeking medical advice for fear of being prosecuted). Contra, Robinson, "AIDS and the Criminal Law: Traditional Approaches and a New Statutory Proposal," 14 *Hofstra L. Rev.* 91 (1985) (proposing legislation criminalizing certain sexual behaviors as best way to modify individual behavior, in order to reduce the rate of spread of the AIDS virus infections.)

III. A Legal Case Study: Hospital Testing and Legal Hazards

A. The World of Testing. The desire of employers, insurers, health care providers and others to test individuals for AIDS is growing. In the *Journal of the American Medical Association,* Jan. 8, 1988, an article appeared entitled "Analysis of the Use of HIV Antibody Testing in a Minnesota Hospital." The authors studied the clinical use of HIV antibody serology at one 450-bed medical center. The results were surprising. The authors concluded:

1. "Only 10% of tests performed fulfilled the criteria for an appropriate test (where the test was indicated and consent and counseling were provided with documentation in the medical record.)"
2. "In 44% of the tests performed, the patient had no recognized factor for acquiring HIV infection."
3. "In an additional 44% of tests performed, the test was medically indicated but patient consent and counseling were not documented in the medical record."
4. Errors were common. Eleven patients were tested, with no record of who ordered the test or why. With six patients, a positive ELISA result was interpreted by physicians as a positive test, in spite of a negative Western Blot. In five patients, asymptomatic seropositive HIV patients were diagnosed as having AIDS. In one case, a patient specimen was mislabeled.

Other studies have confirmed the extent to which physicians and health care professionals generally are poorly informed about the meaning of a positive HIV serotest. See for example Searle, "Knowledge, Attitudes, and Behavior of Health Professionals in Relation to AIDS," *The Lancet* (January 3, 1987) at 26 (surveying English doctors). It is to be hoped that in the year that has passed much of this ignorance has vanished.

B. The Nature of the Risk. Some health care professionals are clearly at increased occupational risk compared to other professions, because of the risk of exposure to patient blood products. The risk may be overstated, however. A recent study of dental professionals, a group assumed to be at high risk, suggests that the risks may not be as high as thought. Klein, et al, "Low Occupational Risk of Human Immunodeficiency Virus Infection Among Dental Professionals," 318 *N. Eng. J. Med.* 86 (Jan. 14, 1988).

Dental professionals are often exposed repeatedly to persons who are HIV positive for months or years before the patients know they are positive. Accidental parenteral inoculations and splashes and aerosolizations of blood and saliva are common. In the author's words, dental professionals are "...a 'sentinel' population that is likely to indicate the maximal anticipated rate of occupational risk for health care workers in general." The study conclusions were as follows:

"This study demonstrates that despite infrequent compliance with recommended infection-control precautions, frequent occupational exposure to persons at increased risk for HIV infection, and frequent accidental parenteral inoculations with sharp instruments, dental professionals currently are at low occupational risk for HIV infection".

The authors noted that risky patients cannot be detected reliably, and that infected persons may not feel or appear ill. They may not want to inform the dentist or may not consider themselves at high risk. Testing takes time, requires confirmatory testing, and may yield false negatives. "Therefore, routine practices to prevent occupational infections should be formulated with the idea that all patients have the potential to transmit infection. ...Strict adherence to recommended infection-control guidelines for dental professionals should help to minimize the risk of occupationally acquired HIV infection."

The same recommendation should apply to hospital personnel. In Searle's words:

"...in view of the fragile nature of the virus outside the body, the large volume of evidence indicating an extremely low risk of transmission in the hospital, the certainty of not being able to identify which patients are in high-risk groups, and the danger of forcing homosexuals to seek help elsewhere, it seems most appropriate to adopt hepatitis-B-level precautions in all situations involving possible contact with body fluids that may contain virus."

The conclusion of the Task Force on AIDS of the University of California, San Francisco, strongly reinforces this position:

"HIV is not readily transmitted to health care workers, even after accidental parenteral exposure to infected blood. Existing guidelines for reducing exposure to blood and other body fluids will protect workers who care for patients infected with this pathogen."

Why should a lawyer suggest such an approach to what is arguably a medical problem? Because it is not a medical problem but rather a complex medical-legal-public health problem. The legal ramifications of various legislature choices support the position that screening should be very limited in the absence of patient consent.

I believe therefore that the following principle should guide legislation in this area. *No HIV test should be ordered until physicians understand the appropriate use of and potential adverse consequences of the HIV-antibody test, have provided complete counseling to their patients, and have obtained the patient's written informed consent to the test.*

This principle strikes a balance between valuable uses of such test results and the downside risks.

C. The Legal Hazards of Overbroad Testing. Tort law in this area is based upon social norms that we as a society value: individual autonomy in decision-making about the body and the self, even if others find those decisions irrational; the right to full information before making difficult medical choices; the right to control information about oneself that can prove destructive if generally known. Tort law and constitutional law both subject individual and government behavior to the test of reasonableness: what is gained and what is lost by the suspect conduct? The burden of justification lies with the proponent of an invasive and potentially harmful approach. Testing blood samples of a suspected HIV-positive individual must therefore pass the test of "reasonableness" before a defendant in a tort case can avoid liability, and before government action can mandate such testing. The privacy interests of the individual are important and powerful interests that deserve substantial protection.

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Blood testing is not considered a minimal intrusion in the constitutional arena. Courts have found significant an individual's interest in maintaining privacy in personal information contained in bodily fluids, *Railway Labor Executives Association v. Burnley,* 1988 WL 8808 (9th Cir. Cal. 1988); *Tucker v. Dickey,* 613 F. Supp 1124 (W.D. Wis. 1985) (urinalyses and body cavity searches equally degrading). In the criminal law setting, testing of the blood for drugs has been circumscribed under the Search and Seizure constraints of the Fourth Amendment. "Particularized suspicion" had been held to be essential before toxicological testing of railroad employees is permissible; and broad based testing without such particularized suspicion has been frequently disapproved.

In the private arena, where constitutional constraints do not apply, the reasonableness principle of tort law combines with a strong judicial bias toward protection of individual autonomy in medical decisionmaking. Given the pernicious consequences that might flow from blood testing of suspected HIV-positive individuals, the courts are likely to impose a stringent burden on the defendants where plaintiffs are in fact injured.

Suppose that a hospital has a policy of allowing testing wherever a health care worker—nurse or doctor—has come in contact with patient blood. Many health care providers would like such a right—to test without the patient's permission. If the Minnesota study previously cited is at all representative of hospital practice around the country, then some of the test results will be misread, and some testing errors will also occur.

Errors in testing can result in a large damage claim. If a patient who tests positive is mistakenly interpreted as HIV positive, even though a followup test is negative, or a seropositive HIV patient is misdiagnosed as having AIDS, or the test is simply wrong, the resulting mental distress of that patient may be compensable in a tort suit. Given the nature of AIDS, such distress is foreseeable to a physician. (See, e.g., Holland, J., Tross, S. "The Psychosocial and Neuropsychiatric Sequelae of the Acquired Immunodeficiency Syndrome and Related Disorders," Ann. Intern. Med. 1985; 103: 760-764).

A physician has been held liable for erroneously informing a patient that she had tuberculosis, resulting in tuberculosis phobia. (*Kraus v. Spielberg,* 37 Mis. 2d 29, 236 N.Y.S. 2d 143 (1962)). A false or erroneous test result may trigger "AIDS anxiety" with debilitating effects on a patient, rendering a health care worker liable.

Overbroad testing by health care workers to alleviate their own anxieties about exposure to AIDS will do little to calm them, while exposing them to tremendously increased potential for tort suits. Patients are put at risk unnecessarily, and so are medical staffs.

If an unconsented-to test result is erroneously read, or a result is wrong, and the patient is notified, a new cause of action is created for the distress caused by the inaccurate news. Overbroad testing of a large group of low-risk patients will increase the error rate and the chances of suit.

If the testing is bootleg, with the patient not notified, and the results are positive, then a diagnosis is missed that could have led to positive medical action at the early stages of seropositivity. The courts' reactions in such a situation have been quite consistent: compensation has been awarded for any mental distress and psychic injury suffered by the patient, and also for the "loss of a chance" of treatment. (*Chappel v. Master,* 255 So. 2d 546 (Fla. 1972) (failure to communicate to prospective adopting parents that child was affected with fatal hydrocephalus held actionable). As more effective palliative treatments develop for the early stages of AIDS with AZT or other drugs, or prophylactic treatments are tried once the patient is seropositive, failure to let a patient know will increase health care provider liability risks.

This will also be the situation where the test, without patient consent or against the patient's desires, is least likely to be disclosed to the patient, because of the health care worker's expectation of patient hostility.

If bootleg testing is in error, and the patient not told, and the results somehow revealed to others, the patient might suffer economic injury and personal harm. The health care provider is ultimately liable for revealing such information and causing these results.

There is an interesting twist to overbroad testing and the increase in the

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risk of suit. If a patient is offered a test after counseling, and declines, then the health care worker does not have information about the presence of HIV or AIDS in that patient. The obligation stops there. If however the provider tests a patient's blood and the test is positive, then must that provider warn the patient? Of course, since the provider now has information that can lead to injury to others if they are not informed if he does not inform the patient and explain how to minimize harm to third parties through safe sex and sterile needles, then an infected third party has a suit against the provider. This *Tarasoff* obligation to warn third parties may extend even further the risks of unconsented to testing. All of this points to the importance of patient consent and adequate counseling and followups with patients, whenever possible.

Routine screening in the health care institution, in order to relieve staff anxiety, is a bad idea. Testing without patient consent is a bad idea. The best justification for screening, if any, applies to carefully circumscribed categories of patients that typically include transplantation patients and high risk prenatal patients. The purpose of such screening is to help in the management of the patient rather than to protect staff. Staff protection is best achieved by a general practice of using precautions in any situation where medical personnel might come into contact with patient body fluids.

Health care providers should test only with the consent of the patient. This avoids most of the liability hazards, follows the practice of several states, such as Illinois and Minnesota, and minimizes the destructive side effects that inadvertent or intentional breaches of confidentiality might have on a patient's life.

The recommendations of Searle and others are relevant here: "...those professionals who do not believe that informed consent is essential before HIV serotesting are risking many difficulties for their patients, and perhaps also medicolegal hazards for themselves."

III. The Constitutional Issues.

A. The constitutional questions raised by AIDS revolve around Due Process and Equal Protection scrutiny of state action to regulate individual behavior. Most academic discussion has looked at the extreme cases of quarantine of infected populations, prison populations, and drug testing in the workplace. The Supreme Court has not considered a case directly involving AIDS, although the *Arline* case comes close in its protection of the employment setting for someone with tuberculosis.

The traditional constitutional doctrine accords deference to state action in the area of public health regulation. The classic decision has been *Jacobson v. Massachusetts,* 197 U.S. 11 (1905), upholding a Cambridge ordinance requiring mass public vaccination to prevent the spread of an epidemic. The case is cited as an example of the high level of deference shown toward public health measures, with such measures treated as presumptively valid. Even this deferential view has been tempered by some constraints on state regulations. Courts will look beyond the stated purpose to question the true legislative purpose. Thus a provision motivated largely by homophobia would probably be struck down.

Jacobson recognizes that there must be a substantial relationship between the control measures and the underlying public health objectives. Later case law in the 1960s and 1970s expanded both Due Process and Equal Protection requirements so that any legislation affecting "suspect classes" would be subject to heightened scrutiny.

The test of the "least restrictive alternative" might be applied to regulatory measures to control AIDS. Certainly the measures adopted may not be unreasonably obtrusive or go "far beyond what was reasonably required for the safety of the public." (*Jacobson,* 197 U.S. 11, 28). For an extensive discussion of the constitutional dimensions of AIDS, see Curran, W.J., Gostin, L., and Clark, M. *Acquired Immunodeficiency Syndrome: Legal and Regulatory Policy* (Washington, D.C.: US Public Health Service, 1986).

B. Mandatory testing programs have not yet been fully explored by the Supreme Court, but the new 9th Circuit decision in *Railway Labor Executives Association v. Burnley,* 1988 WL 8808 (9th Cir. Cal. 1988) recently held that "particularized suspicion is essential to finding toxicological testing of railroad employees justified at its inception.... Broad based testing, without particularized suspicion...has been frequently disapproved." ■

Summary

We need a balanced legislative and judicial response to the problem of AIDS. The intense anxiety of prison officials, health care professionals, employers, and others is understandable, in the face of the risks. Such anxiety however can lead to extreme and unreasonable responses if not tempered by a balanced appraisal of the risks.

The legal system's touchstone for evaluating calls to action is the test of reasonableness. Might the proposed state action do more harm than good—to the individual affected; to that person's family, friends or lovers; to society? Does the action create unanticipated side effects? The advocates of intrusive state action need to justify their demands with reference to these principles. The burden of proof is on them.

We should protect patients from being tested against their wishes, since testing for HIV positivity is distinguished from other forms of testing by the potential social repercussions if the results leak out. We should aim to protect patients from disclosure by others of their HIV status, whether inadvertent or intentional.

We should also insure that resources are available to help health care providers counsel their patients and treat them. Those physicians, dentists, and allied health professions in the State of Delaware who are actively involved in caring for HIV positive patients are to be commended for their efforts. But they need more help. The State needs to expend more efforts in counseling the citizens of Delaware about the risks of HIV, and making available the information and the means for protection. Financial support for the treatment and sustenance of those with AIDS is needed. We as a society have an obligation to help, overcoming our own fears in order to extend our support to those who suffer.

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Flying Blind: The Insurance of Concealed Risks

Michael J. Bartholomew

AIDS is potentially the most serious health threat our country has ever faced. It is now conservatively estimated that AIDS has afflicted 57,000 Americans and, according to *very* conservative estimates, may afflict as many as 270,000 people in the year 1991, causing an estimated 179,000 deaths.[1] Most of these deaths will occur among the predicted 1.5 million Americans already infected with the virus, many of whom show no signs of illness.[2] Great as the danger of this disease to life itself may be, it poses a corresponding threat to the country's financial well-being and the solvency of the health care system. Unfortunately, in some instances legislatures have enacted measures that mandate the abandonment of time-honored principles of underwriting, thereby endangering the financial stability of many insurance companies.

Estimates by the U.S. Public Health Service put the annual direct cost of health care for the estimated 171,000 AIDS patients in the year 1991 between 8 and 16 billion dollars,[3] assuming a cost per case of $46,000 to $92,000.[4] Other studies predict a considerably higher cost, and only a rare few (e.g. San Francisco) have shown a lower per case cost.

While these figures are high, they do not take into account the cost of outpatient care, counselling, and home health care. In addition, they do not reflect loss of income due to disability, and they do not measure in any way the impact on the life insurance business. Insurers expect to pay billions of dollars for AIDS-related claims over the next several years as they fulfill contractual obligations to policyholding AIDS victims.

Insurance is founded on the principle that insureds with the same risk of loss should be treated equally. AIDS virus infection, now known to be a highly significant risk factor, cannot be ignored by any actuarially sound insurance system. However, state legislatures moved by sympathy for persons with AIDS, are continuing to give serious consideration to a prohibition on the use of AIDS-related testing for insurance purposes: a ban that would seriously distort the equitable functioning of the insurance system in pricing its products.

Insurance underwriting is defined in general terms as the "process by which an insurer determines whether or not and on what basis it will accept an application for insurance."[5] The primary goal underlying this process is an accurate prediction of future mortality and morbidity costs. In carrying out this process, moreover, an insurer has the responsibility to treat all its insureds fairly by establishing premiums at a level consistent with the risk represented by each. It is basic to providing insurance for people of different ages, genders, jobs, and medical histories, that an insurer create classifications to recognize the many differences that exist among them. Those differences very often affect risk assessment. Such things as age, medical history and general physical condition, gender, occupation, the use of alcohol and tobacco are analyzed separately and in combination to determine their effects on a person's longevity.[6] Understanding the way in which these various characteristics influence mortality assists insurers in classifying insurance applicants into groups with comparable mortality risks and in establishing appropriate premium rates.

About 158 million Americans under the age of 65 are covered by some form of group health insurance, and an additional 9 million by individual health policies.[7] Unlike individual insurance underwriting, group underwriting involves an evaluation of the risk of a *group;* the most common example being a group of employees. This evaluation establishes the terms of an insurance contract acceptable to the insurer.[8] Unlike those writing individual policies, group insurers consider only the relevant characteristics of the group, operating on the premise that any large group will contain a few individuals who have medical conditions of such severity as would make them either substandard or uninsurable risks if they were to be subjected to individual underwriting standards.[9] It should be noted also that in certain instances,

group insurers do resort to individual underwriting methods (a) for small groups, (b) for those who enroll late in a plan or (c) in instances where would-be insureds apply for large supplemental amounts of life insurance beyond that given to them as part of their general eligibility under the plan.

Thus the issue of testing for the presence of the AIDS virus or the active presence of AIDS relates only to new coverage for which the insurer requires evidence of insurability of each person to be insured.

As mentioned above, an integral part of the insurance pricing system is the ability to inquire into characteristics of individual applicants in order to place them in groups with comparable mortality. This process thus makes distinctions between those in different classes or discriminates in the way in which these classes are established.

It is just this process of discrimination that is the cornerstone of insurance regulation. The Unfair Trade Practices Act developed by the National Association of Insurance Commissioners established statutory rules requiring the fair and equitable treatment of insureds in the underwriting process. By 1960 just about all the states and the District of Columbia had enacted some form of this Act. Its essential tenet, of course, is the distinction between fair and unfair discrimination. To discriminate in this sense is *not* pejorative, but in neutral dictionary sense, "to mark or perceive the distinguishing or peculiar features of...", or "to distinguish or differentiate". For example, under the Act it is deemed inequitable to charge a 60 year old male in poor health and a 20 year old female in good health the same premium for an individual life insurance policy. In such an instance an insurer must *differentiate* between these two persons to determine equitable premiums for each. It is thus appropriate that the rates in these instances should be adequate but not excessive and should discriminate fairly between the insureds so that each will pay according to the quality of his or her risk.[10]

In the same context, the Act prohibits an insurer from *"making or permitting any* unfair *discrimination between individuals of the same class and equal expectation of life in the rates charged for any contract of life insurance." (italics supplied)* There is a similar provision for health insurance. It is thus the contention of the insurance industry that persons who have been infected by the AIDS virus are not of the same risk and class as those who have not been.

"Fairness" has often been litigated. In a 1974 case,[12] a Pennsylvania state court upheld a ruling of the Insurance Commissioner, which had revoked approval of several health insurance policy forms on the theory that the low premium charge in the first month of coverage had no actuarial relationship to the actual risk and was therefore discriminatory. The principle is clear: under the Act an insurer must accord similar treatment in the underwriting process to those representing similar risks.

To ignore the levels of risk associated with AIDS infection and to treat a person who tests positive on an AIDS test the same as one not similarly infected would clearly constitute unfair discrimination against those not infected and would violate the states' Unfair Trade Practices Acts.

In 1986 the state of Washington became the first state to apply its Unfair Trade Practices Act to the underwriting of AIDS. The Insurance Department promulgated a rule[13] stressing the mandate of the Act that underwriting considerations for AIDS must be consistent with underwriting considerations for other diseases. This regulation underscores the real duty that insurers have to separate insureds with identifiable serious health risks from the pool of insureds without those risks. Failure to do so represents a forced subsidy from the healthy to those less healthy. To meet the fundamental fairness requirements of the Act aimed to address the concern for unfair discrimination, insurers must continue to use objective, accurate, and fair standards for evaluating the risk of AIDS. For the insuring process to remain fair to all applicants and insureds, insurers must be permitted to treat tests for infection by the AIDS virus in the same manner as they treat medical tests for other diseases. To ignore the levels of risk associated with AIDS infection and to treat a person who tests positive on an AIDS test the same as one not similarly infected would clearly constitute unfair discrimination against those not infected and would violate the states' Unfair Trade Practices Acts.

It is now generally accepted by medical authorities that the protocol of body fluid tests known as the "ELISA–ELISA–Western Blot" series is highly accurate for determining the presence of infection with the HIV virus.[14] In addition to findings by the National Institutes of Health, other evidence of the reliability comes from the epidemiologist for the state of Wisconsin who was directed by statute[15] in 1986 to determine whether any test or series of tests "was medically significant and sufficiently reliable" for detecting the presence of antibodies to HTLV-III. That epidemiologist concluded that the ELISA–ELISA–Western Blot series was "medically significant and sufficiently reliable" for detecting the presence of the HTLV-III antibody.[16]

It is the practice in the industry to administer this protocol rather than a single test to identify HIV infected applicants for insurance. Once an individual has been reliably identified as infected with the virus, it is conservatively estimated by the United States Center for Disease Control that an individual likelihood of contracting AIDS within five years can be estimated at 20 to 30 percent.[17] More recent studies estimate the risk as high as 50 percent within a span of ten years.[18] It is a stark reality that no one unequivocally diagnosed as suffering from AIDS has ever recovered, and most victims die within two to three years of the onset of disease.

The significance of these facts is difficult for the insurance industry to ignore. Using the most conservative estimate of the Centers for Disease Control of 20 percent—translates into numbers such as 200 persons out of each 1000 applicants who test positive as developing AIDS within five years and dying within seven. By contrast, mortality tables for life insurance estimate that a standard group of 1000 persons who are age 34, only 7.5 will die within seven years from all causes.[19] Thus, a person testing positive for AIDS is 26 times more likely to die within seven years than a person not infected, all other risk factors being equal. By further contrast, consider that a smoker is only twice as likely to die within seven years, a person with diabetes is four times more likely, and a person who has suffered a prior heart attack is five times more likely. The actuarial significance

(Continued on next page)

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Flying Blind
(continued)

of these facts is overwhelming and cannot be ignored. Because such tests are reliable, accurate, and effective predictors of risk, they must be considered proper underwriting tools.

Until the recent controversy over AIDS, insurers have generally been given the right to inquire into and test for medical conditions shown to have an effect on mortality and morbidity. However, recently there has arisen a fundamental misunderstanding of insurance principles along with a desire to prevent discrimination against homosexuals, which in turn has lead to the passage of laws or regulations in jurisdictions granting those infected with AIDS a favored status in the underwriting process. These laws substantially impede our industry's ability to evaluate risk and undercut the industry's financial stability and compromise its ability to pay future claims.*

For example, in 1985 California enacted a law providing that "the results of a blood test to detect antibodies to the probable causative agent of Acquired Immune Deficiency Syndrome ... shall not be used in any instance for the determination of insurability or suitability for employment."[20] Likewise, in the same year Wisconsin enacted a similar but more restrictive law.[21] In 1986, the District of Columbia passed the most restrictive legislation of its kind in the country, prohibiting the use of *all* AIDS-related tests for a period of five years including tests for the AIDS antibody, tests to appraise the condition of the immune system, and tests to identify the existence of the AIDS virus itself.[22] The American Council of Life Insurance and the Health Insurance Association of America brought suit against the District, arguing that the Act violated both the 5th Amendment of the United States Constitution and the Home Rule Act of the District of Columbia.[23] Regrettably,

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the District Court declared the Act valid because the evidence presented by the ACLI and HIAA at trial was not similarly available to the City Council at the time the bill was under consideration.[24] The court otherwise appeared to agree with the plaintiffs that presently available evidence refuted the allegations made by the City Council that the test was unreliable, inaccurate, and of no predictive value.

This decision, while unfavorable to the industry, does seriously call into question whether similar legislation will pass constitutional scrutiny in light of the medical and scientific information supporting the credibility of the ELISA–ELISA–Western Blot series.

The major goal of legislative attempts to restrict insurers' rights to tests has been to prevent insurance companies from discriminating against homosexuals. The life and health insurance industry approve that principle: in fact they have endorsed guidelines adopted by the National Association of Insurance Commissioners in December of 1986 that set forth two general propositions:

1. No inquiry in an application for insurance coverage or an investigation conducted by an insurer or a support organization on its behalf in connection with an application for insurance shall be directed towards determining the applicant's sexual orientation, and

2. Sexual orientation may not be used in the underwriting process or in the determination of insurability.[25]

The insurance industry are in substantial agreement that sexual orientation of an applicant is not an appropriate underwriting tool and are equally strong in their agreement that current state of the art tools for predicting the AIDS risk are valid for that purpose and should be used accordingly in a responsible fashion.

In its support of these guidelines the industry refutes the contentions of certain groups that sexual orientation has a place in the underwriting process. Rather, we seek only to use the best medical knowledge available to evaluate the level of risk an applicant represents. The insurance industry are in substantial agreement that sexual orientation of an applicant is not an appropriate underwriting tool and are equally strong in their agreement that current state of the art tools for predicting the AIDS risk are valid for that purpose and should be used accordingly in a responsible fashion.

As I have stated previously, without the ability to properly assess risk insurance companies are left without the valuable tools needed to do a proper job in the conduct of the business of insurance. One of the real dangers that arises in such an environment is adverse selection. Adverse selection can be defined as the tendency of persons with poorer than average health to apply for or to renew insurance to a greater extent than persons with average or better health.[26] Such a process, of course, results in unfair and inequitable treatment of healthy people because it results in their subsidizing those at high risk. Practically speaking, insurance companies generally are not faced with the underwriting challenge of determining whether an applicant does or does not have full-scale AIDS. People are more likely to want to buy insurance at the outset of their infection when they already represent a very high level of risk, but present few symptoms. Thus the main underwriting challenge facing insurers is that of identifying people in earlier stages of the disease.

Strong evidence already exists of AIDS-related adverse selection against insurers. In 1985 the HIAA and ACLI initiated just such a survey of its member companies.[27] The results found claims for life insurance to be heavily concentrated in the first two years after issuance of policies. This pattern strongly suggests that these insureds knew or suspected that they had been infected by the AIDS virus before they purchased insurance. This adverse selection not only endangers the financial stability of insurance companies, but unfairly burdens the other policyholders who must support the increased claims through higher premiums.

Adverse selection can usually be combatted by mechanisms designed to protect insurers from such events. However, the uniqueness of AIDS significantly dilutes the effectiveness of these

(Continued on page 67)

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(continued)

mechanisms and renders insurers especially vulnerable to adverse selection.

Public health authorities have stated that the latency period between infection and overt AIDS averages four or more years in adults.[28] Individual life and health policies contain a clause that permits the coverage issued to be contested during the life of the insured for a period of two years from its date of issue.[29] Also, even assuming that an insured's misstatements about his or her health are discovered within this two year period, in most jurisdictions the insurer must show that the misrepresentations, omissions, or incorrect statements were fraudulent; or that they were material to the acceptance of the risk; or that the insurer, in good faith would not have issued the policy at the same premium rate or at all if the truth had been made known.[30] Also, insurers have the additional burden of knowing that actual fraud cannot be a basis for contest once the incontestability clause takes effect in some states.[31]

Because the fear of AIDS is very real for certain groups in our society, life insurance applicants who believe they have been infected with the virus may very well misrepresent their health history or present physical condition when applying for insurance.

Because the fear of AIDS is very real for certain groups in our society, life insurance applicants who believe they have been infected with the virus may very well misrepresent their health history or present physical condition when applying for insurance. These misrepresentations would normally be grounds for rescission of the policy. However, after the period of contestability has passed, benefits could not be denied on the ground that poor health or medical disability existed at the time the policy was issued.

Given the recency of the disease, state and federal courts are just now beginning to decide law suits arising from AIDS-related claims for insurance benefits. In a recent suit on a $100,000 life insurance policy the U.S. District Court in Alabama found for the beneficiary. The insured had not known he was suffering from AIDS when he applied for and received delivery of the policy. He had had lesions on his skin the same day the policy was issued. Almost a week after the policy was issued the insured was diagnosed as having Kaposi's sarcoma. The federal court required the insurer to pay the benefits under the policy, ruling that there was no material misrepresentation in the application even though the insured had not disclosed consulation with a doctor for skin lesions two weeks before he applied.[32]

The average latency period of four years for AIDS and legislative prohibitions against insurance-related testing, make it relatively simple for someone aware of his health status to misrepresent that knowledge to an insurer with some confidence that the incontestability period will lapse before the appearance of symptoms that would otherwise alert the insurer to the possibility of that misrepresentation.

As a proponent of AIDS-related blood testing to ensure the equitable treatment of all applicants for insurance in the underwriting process, I must address one inevitable and unfortunate consequence of effective underwriting—the denial of health insurance to some high risk applicants, particularly those with HTLV-III infection.

For those covered by group health insurance, various state laws operate to prevent interruption in coverage when an insured is no longer eligible for group insurance. The availability of continued coverage was also significantly bolstered by the 99th Congress in its enactment of COBRA.[33] This federal law now requires in most instances that employers of 20 or more employees provide a continuation of health coverage for up to 18 months following termination of employment. Given that most AIDS patients live no longer than two years following manifestation of the AIDS-related diseases, these continuation requirements effectively assure protection against the catastrophic costs of AIDS.

Even though a majority of Americans have group health coverage, some do not have such access and are medically uninsurable for individual coverage. Included in this group along with AIDS victims are those with developmental disabilities, chronic health conditions or other serious impairments. They are estimated to number around one million.

Many argue that the insurance industry should suspend its underwriting system and assume all future health care costs of AIDS patients. While those afflicted do need access to quality care, this approach shows a basic misunderstanding of the insurance process and does not make any provision for the receipt of premiums sufficient to cover expected claims. If insurers cannot collect premiums in amounts sufficient to handle the underlying risk, simple arithmetic would tell us all that there won't be enough money to pay the submitted claims and many insurers could be placed close to insolvency. Indeed if such a solution were adopted it would mean that insurance need only be purchased after the development of an illness, thus abandoning any method of risk assessment as presently practiced. Such a policy could have grave consequences for the U.S. health care system.

One solution alternately suggested is the establishment of state run risk pools

(Continued on next page)

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for the uninsurable. Fifteen states already have established such pools by statute. A glaring problem exists however with their funding mechanism. With the exception of Illinois, losses are shared by health insurance providers and not through general state revenues. Since ERISA effectively prevents state assessments against employee welfare benefit plans that are not funded by insurance plans,[35] employers who administer such arrangements are shielded from the assessment visited by the pool on insurance companies, Blue Cross/Blue Shield, and HMOs.

Pools need to be established, we believe, with the assistance of the federal government, to ensure that the social responsibility of providing coverage to those not insurable because of health condition would be fairly apportioned. A bill introduced by Sen. Heinz and Rep. Kennelly in 1985 would have, if passed, imposed a tax on employers not voluntarily participating in state pools meeting certain minimum standards.[36] Legislation that imposes participation in pools only by health insurers shifts an unequal and unfair responsibility for the provision of health care expenses upon our industry, a responsibility that should be shared by all.

In concluding I wish to emphasize that in order to operate effectively in a voluntary market, insurance underwriting must be able to appraise the risk of an unknown and unanticipated occurrence and spread that risk over a large number of individuals as accurately as possible, because the whole price structure of insurance depends on the principle that those who present the same expected risk of loss pay the same premium.

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Contrary to this principle, however, some jurisdictions have imposed legal constraints that place AIDS outside the normal medical and regulatory rules pertaining to underwriting for other diseases. It is no overstatement to say that the principal purpose and effect of these measures will be to elevate and single-out HIV carriers for a level of regulatory treatment and protection unavailable to any other group under the insurance laws and regulations of this country. Although it is legally permissible for an insurer to obtain medical information about an applicant who may contract any other disease, such as heart disease or cancer, some states grant AIDS carriers special treatment by completely exempting them from relevant tests.

Although the industry is fully cognizant of the concerns of AIDS victims, it must also consider its responsibility to those who have *not* been infected. If the projections of AIDS cases materialize, public policy makers will be faced with an increasingly pressing need to achieve a balance between competing concerns. This balance need not, and indeed should not, be achieved at the expense of an industry that will inevitably bear a substantial amount of the costs associated with the AIDS crisis. ■

[1]See U.S. Public Health Service, Public Health Service Plan for the Prevention and Control of AIDS and the AIDS Virus 5 (Coolfont Planning Conference June, 1986) (cited hereafter as Public Health Service Plan)

[2]See *Id.*

[3]Institute for Medicine, National Academy of Sciences, Confronting AIDS: Directions for Public Health, Health Care and Research 21 (1986) (hereinafter as Confronting AIDS)

[4]See Public Health Service Plan, at 15.

[5]Health Insurance Association of America, *A Course in Group Life and Health Insurance,* A p. 379 (1985) (hereinafter HIAA, 1985)

[6]See R. Mehr, E. Camaak & T. Rose, *Principles of Insurance* 657-59/8th ed. (1985)

[7]Health Insurance Association of America, *Source Book of Health Insurance Data: 1986 Update 6.*

[8]See HIAA, 1985 supra note 5, at 153.

[9]*9Id.*

[10]Bailey, Hutchison & Narber, *The Regulatory Challenge to Life Insurance Classification,* 25 Drake L. Rev. 779, 782; accord Thompson v. IDS Life Ins. Co., 274 Or. 649, 654, 354 P.2d 510, 512 (1976).

[11]National Association of Insurance Commissioners, An Act Relating to Unfair Methods of Competition and Unfair Deceptive Acts and Practices in the Business of Insurance, 1972 Proc. NAIC I 493, 495.

[12]Physicians Mutual Insurance Co. v. Dinenberg, 327 A.2d 415 (1974).

[13]Wash. Admin. Code §284-90-010(2) (eff. 11/14/86).

[14]See J. Slaff & J. Brubaker, *The AIDS Epidemic 201* (1985) (citing Dr. Robert Gallo, National Institutes of Health researcher and co-discover of the HTLV-III virus).

[15]Wisc. Stat. Ann. §631.90(3) (a).

[16]J. Davis, Serologic Tests for the Presence of Antibody to Human T-Lymphotropic Virus Type III: Information Pursuant to the Purposes of Wisconsin Statute §631.90 Regarding Their use in Underwriting Individual Life, Accident and Health Insurance Policies 22 (Wisc. Dept. of Health and Social Services, 1986).

[17]Public Health Service Plan, Supra note 1, at 5.

[18]Confronting AIDS, Supra note 3, at 7.

[19]Society of Actuaries, Transactions: 1982 Reports of Mortality and Morbidity Experience S5 (1985).

[20]California Health & Safety Code §199.21 (f) (West Supp., 1986) (eff. 4/4/85).

[21]Wisc. Stat. Ann. §631.90 (West Supp. 1986) (eff. 11/23/85).

[22]D.C. Law 6-132, 33 D. C. Reg. 3615-24 (1986).

[23]American Council of Life Insurance v. District of Columbia, 645 F. Supp. 84 (D. D.C. 1986).

[24]*Id* at 87.

[25]Advisory Committee on AIDS, National Association of Insurance Commissioners, Medical/Life style questions and Underwriting Guidelines (1986), §I(A), (B).

[26]HIAA 1985, Supra note, pt. A at 347.

[27]American Council of Life Insurance & the Health Insurance Association of America, AIDS Survey of Member Companies 2 at I.

[28]Public Health Service Plan, Supra note 1 at 5.

[29]See, e.g., 18 *Del. C.* §2920.

[30]See, e.g., Hyman v. Life Ins. Co. of N. Amer., 481 F.2d 441 (5th Cir. 1973).

[31]43 Am. Jur. 2D Insurance §768 (1982).

[32](Kentucky Central Life Insurance Company v. Webster (N.V. Ala. 1986) 651 F.Supp. 935).

[33]Consolidated Omnibus Reconciliation Act of 1985, Pub. L. No. 99-272 §§10001-10003, as modified by Pub. L. 99-514 and Pub. L. 99-509.

[34]Con., Fla., Ill., Ind., Iowa, Minn., Mont., Neb., N.D., Tenn., Wisc.

[35]See specifically 29 U.S.C. §1144.

[36]H.R. 1770, S. 1372, 99th Congr. 1st Sess. (1985); see also 99th Congr., 2nd Sess. 14(1986) (Statement of Sen. Heinz).

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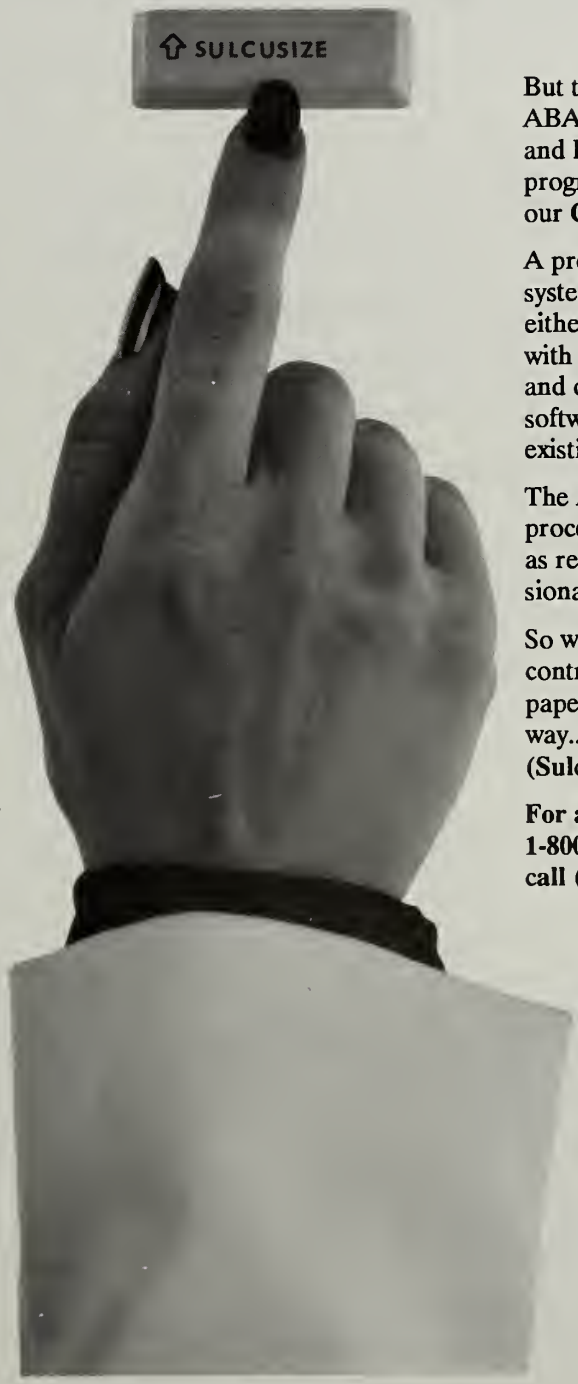

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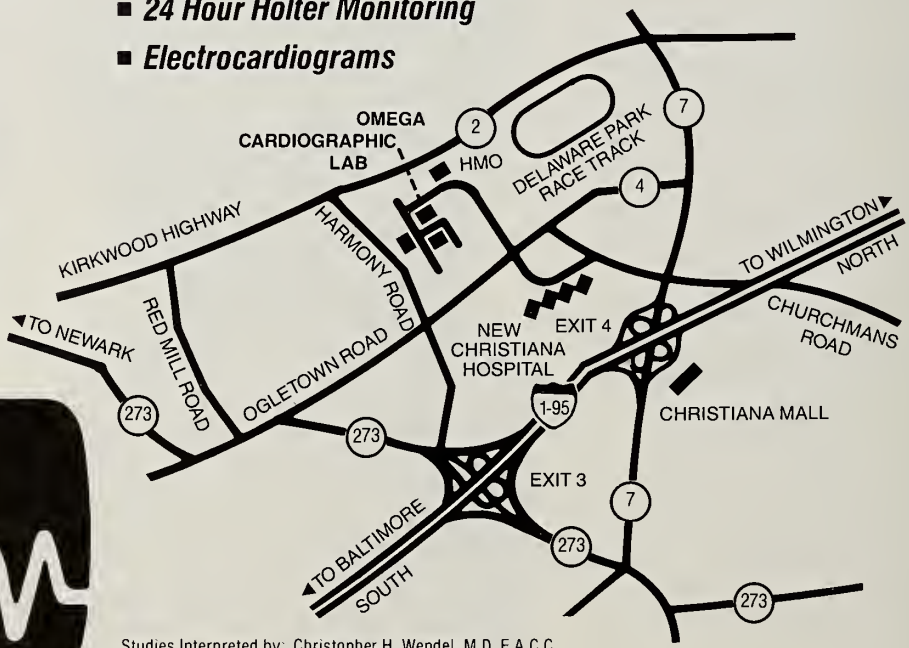

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The Department of Justice: Dealing with A Constellation of Problems

David J. Lyons

As a Deputy Attorney General I represent the Division of Public Health, and in that capacity I've had the opportunity to become acquainted with various issues surrounding AIDS. I do not pretend to any exalted expertise on AIDS. Instead, I see myself as a "conspicuous student of the disease" and its various ramifications. In that role I have come to be characterized in the Department of Justice as the "AIDS" Deputy. I'm a sort of clearinghouse, providing resource materials so that the other deputies can try to answer questions reasonably when they encounter problems with respect to AIDS.

I have a litany or a list of various topics, which I want to address briefly. I think it's important to put as many issues as possible on the table so that we can begin to acquaint ourselves with a very important area of the law, which is developing rapidly.

Biomedical Waste

Under Delaware law infectious wastes are indeed hazardous wastes, and subject to regulation [7 *Del. C.* §6302 (7)]. Until the advent of the AIDS crisis, there was little serious concern about regulating them. Then there were incidents in New Jersey where needles washed up on the beach. Some vials of blood were discovered by children behind a doctor's office in Dover, and people started to become concerned: perhaps we needed to take a look at how we managed and disposed of infectious waste. I've attempted to determine how far along the Division of Public Health and the Department of Natural Resources and Environmental Control have gone in formulating policies with respect to the disposal of such waste. At this point, the process has not evolved very far at all. Dr. David Verma of the Division of Public Health tells me they are currently attempting to determine what guidelines they should follow in formulating the Delaware response to disposal of infectious wastes. These guidelines would of course include 1.) how to segregate wastes, 2.) how to package them and 3.) how to dispose of them.

We're only at the threshold of this issue, but I recognize that the medical community will be faced with regulations that will add expense and employee time to the conduct of practice.

The Handicap Status of AIDS Victims

In September of 1987, the Attorney General announced the receipt from Dr. Lyman J. Olsen, Director, Division of Public Health, of a request for an opinion as to whether AIDS victims would be designated as handicapped under the Equal Accommodations Statute (6 *Del C.* Ch. 45) and the Equal Rights to Housing Statute (6 *Del C.* Ch. 46). In my capacity as the representative of the Division of Public Health, I was asked to initiate and to assist in drafting that opinion.

In doing so, I relied heavily on an opinion of the United States Supreme Court, *School Board of Nassau County Florida, et al. v. Arline,* 107 S. Ct. 1123 (1987), in which a teacher with tuberculosis, claimed that she had been discriminated against under the Rehabilitation Act of 1973 (29 U.S.C.A. §793 *et seq*). In reviewing the pertinent law, it became apparent that the federal and state definitions of the term "handicap" were identical, and that the federal regulations would provide assistance in trying to determine if AIDS, in fact, fell within the definition of the term "handicap" under federal law. We would take our cue from that determination in deciding whether under state law, the same held true. Indeed, we concluded that the federal law *does* include AIDS as a handicap, and we then concluded that under state law an AIDS victim would be accorded protection under the Equal Accommodation Act and the Equal Housing Act.

Having reached that conclusion, we also had to consider whether mere HIV positivity would also qualify as a handicap. We looked at *Arline, supra,* and noted that *Arline,* in talking about the Rehabilitation Act held that, notwithstanding an infected person's freedom from the physical effects of a disease, if he was *regarded* as diseased, he would indeed be suffering the effects of discrimination as a *result* of that disease and should be included within the protected class. We looked at the state law, and noting the similarity of the federal definition to the state law, concluded that those found to be HIV positive should also be accorded handicapped status under Delaware law.

Our opinion does not, however, disregard the circumstances where, for an unrelated lawful reason, a distinction may be properly made between HIV positive individuals or AIDS patients and the population at large. For instance, if someone applies for housing, and the landlord wants to know that a prospective tenant can afford to pay the rent. Similarly if the applicant has a criminal history, that is relevant to the landlord's deciding whether he should expose other tenants to one, who although HIV positive, has also demonstrated violent

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Department of Justice
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tendencies in the past and thus would represent a threat to other tenants. Likewise it might be reasonable for a physician to refer a patient for treatment elsewhere if that physician did not possess the expertise for treating AIDS patients.

Excluding Professionals?

The Equal Accommodation Act makes no express exclusion for professionals such as dentists, doctors, or lawyers so as to negate their coverage under the Act. It is conceivable that in Delaware a dentist, doctor, or lawyer could be the target of a complaint filed with the Human Relations Commission alleging denial of service merely because the complainant had been judged HIV positive. There is no Delaware case law that tells us whether the term public accommodation includes the practice of dentistry, medicine, or law.

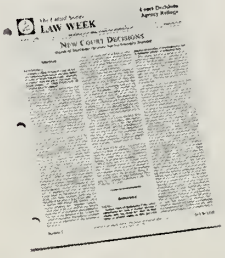
In reviewing the various AIDS advance sheets I receive bi-weekly I noted that the New York City Human Relations Commission recently received a complaint filed on behalf of an AIDS victim alleging that a dentist had discriminated in declining to provide treatment to the sufferer and had referred him elsewhere because he had AIDS.(*AIDS Policy & Law,* March 9, 1988 at p. 4.)

The dentist defended, stating that his decision to refer the patient out had been an exercise of his professional judgment and that regulation of dentistry under state law was the exclusive province of the state education department. The dentist further argued that his office was not a place of public accommodation. Furthermore, if his office *was* a place of public accommodation, his referral was a reasonable accommodation for a person with AIDS. (The patient died five days after the alleged discrimination.)

The administrative law judge concluded that, although the issue of reasonable accommodation was relevant, it was a question of fact that he would have to decide upon hearing the evidence. He further concluded that under the New York City Code medical providers such as pharmacies were in fact places of public accommodation, and he found that the code was also intended to cover professional offices such as dentists'. According to the advance sheet, the defendant's counsel plans to seek a stay of the ruling to challenge the application of the term "a place of public accommodation" to a dentist's office. This case is probably one of the first in the country concerning treatment of AIDS patients. Other jurisdictions may reach different results. For example, unlike the New York law, the Philadelphia Public Accommodations Act contains an exception for professional services, although it is vague and subject to some construction. But let us posit a dentist or a lawyer with a big sign in front of his practice, actively soliciting public patronage generally, rather than by referral. It seems more than likely that such a professional would be found to be running a place of public accommodation. Surely the intent behind those laws was that such services along with other services generally, like access to a McDonald's when and if you please, should be available to everyone.

As of this writing The State Human Relations Commission has received only one AIDS housing complaint, and that an inconclusive one because the complainant died. In other jurisdictions these issues are developing more rapidly. We're going to have to watch this progress in determining a Delaware response. It's apparent to me that sooner or later there will be a large number of people in Delaware afflicted with AIDS,

Decisions, Decisions, Decisions.



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David J. Lyons, Esquire, a member of the Delaware Bar, is a Deputy Attorney General in the employ of the Department of Justice, where he represents the Division of Public Health. He is a graduate of George Washington University and of the Widener University School of Law. Mr. Lyons's article is drawn from his remarks delivered at the Professional Conference on AIDS. His separate review of legislation was prepared subsequent to the conference.

and we're going to have to face these problems. Other jurisdictions are already doing so and we may find the developing precedents helpful.

Criminal Law Enforcement

This again is a somewhat controversial area. To begin with, there's a statute on the books relating to sexually-transmitted disease control (16 *Del. C.* §701 *et seq.*) of questionable constitutionality. It puts all enforcement authority in one administrative officer, who makes decisions with respect to quarantine, testing, and the treatment of those presumed to be infected with sexually-transmitted diseases. There is presently underway, however, a movement to revise the sexually-transmitted disease code (See HB 599, introduced June 2, 1988). We are taking a hard look at reporting requirements (e.g. How soon after a physician's or a laboratory's diagnosis of a sexually-transmitted disease must it be reported to the Division of Public Health?). We expect that new code provisions will inject a neutral third party to review the reasonableness of the public health officer's orders with respect to testing, treatment, and quarantine. Again, these provisions are in the preliminary stage, subject to review by the Office of the Attorney General, and will doubtless undergo changes.

What we propose is that the health officer, upon receiving reliable information, notify a presumably afflicted person that he or she is suspected of suffering from a sexually transmitted disease. That person should be given an opportunity to comply with the directives of the notice, which in the initial stages will probably be confined to testing and treatment.

The proposed legislation will direct the health officer first to seek voluntary compliance to prevent the infection of others before issuing an *order* of compliance to a recalcitrant. Absent voluntary compliance, an order could issue, requiring testing and restricting in a variety of ways, the activities of one who is allegedly infected with a sexually transmitted disease. If the health officer's order were ignored he or she could seek enforcement in court. Of course, the party affected would have an opportunity to contest the entry of such an order.

That statute will also authorize, *inter alia,* the health officer when confronted with an imminent threat to public health, to seek *ex parte* a court order to detain a suspected carrier for 72 hours for testing. It could be used, for example, in the case of a prostitute apparently infected with HIV who continues the practice of prostitution, raising a primary public health concern, and who cannot otherwise be removed from the street quickly without violating his or her rights. Such an order would, of course, be reviewable.

Such legislation *is* controversial. However, its need is very much apparent because in today's society people who are infected with HIV represent a risk to the public at large. If they refuse to alter their behavior, others can become infected. There is a 1985 Florida case [W. Dornette, *AIDS and The Law* 174 (1987)] in which a judge ordered a prostitute to remain in her home and to wear an electronic monitoring device so that the authorities could determine her whereabouts at all times. She had previously demonstrated no concern for the health of others. Infected with HIV, she continued to practice her profession, even though she had been prosecuted several times for prostitution. That's obviously the worst-case scenario.

(Continued on page 75)

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I suspect that our law will not be used very frequently, because most people will alter their behavior upon learning that they are dangerous to others.

Prisons

At this time, the prison system in the state of Delaware is not engaged in any type of mandatory testing, although there is statutory authority for it [11 *Del. C.* §6523(b)]. The decision not to test relates to imperfections inherent in the test, which is not yet so accurate as to allow the conclusion that, if the test is negative, the subject will not seroconvert within the next few days or months. In other words, there's a window phase of approximately of 6-12 weeks between exposure to the disease and the appearance of antibodies.

Secondly, it is thought that it would be expensive and difficult to segregate a group with already demonstrated antisocial tendencies and confine them with a death sentence. It will be very difficult to find people to guard them, and on a more serious note, corrections personnel question whether it's medically reasonable to place those who are just HIV-positive with people who are already sick with the disease.

At this time, although various states have initiated mandatory HIV testing of prisoners, only Colorado tests and segregates those who test positive.

That's not to say, however, that individuals are never segregated in Delaware. I have learned of a prisoner, who, informed that he was HIV-positive, declared that he had no intentions of altering his behavior towards other prisoners. The corrections personnel quite sensibly concluded that they should segregate him.

Finally, prison guards are not notified that a prisoner is HIV positive. However, the guards are told to take bodily fluids precautions when transporting inmates who have been determined to have infectious diseases.

Insurance Underwriting

Delaware has adopted national guidelines with respect to life and health submissions, permitting life and health insurers to test. They must, however, obtain written consent. Furthermore, that test has to be administered in accordance with Division of Public

(Continued on next page)

Just When You Thought It Was Safe to Get Tested

Many of the articles in this issue are drawn from the remarks of experts who spoke on April 16 at the Professional Conference. A great deal has happened in this fast breaking story since then. This magazine does not enjoy the stop press luxury of newspaper publication, but we can slip in a few pertinent references to what's come up in the past few months.

The early summer announcement by the Alfred I. duPont Institute of a blanket policy of rejecting any HIV positive patient demands comment. This action is calculated to worsen a situation that no one would have thought capable of worsening, a piece of Scarlet Letter—Off You Go to Molokai mentality that drives an epidemic underground to work its evil undetected.

Health care professionals can be proud of their colleagues at the Childrens Hospital of Philadelphia, who have challenged this misguided policy. Lawyers can be no less proud of the Attorney General's promise to challenge it in court. His swift and responsible decision is gratifying.

We are convinced that early, open, widespread testing without threat of stigmatic consequences is in everyone's interest: those who can be helped while their infection is still manageable, and who can be helped far better in the light of the fullest medical knowledge of their condition; the health care professional whose risk should be an informed one; the young and sexually active public who will unwittingly contract the virus from partners who will unwittingly bestow it; and, once again, the infected who, paradoxically, may need extra protection against the *healthy*, who are loaded with bacteria dangerous only to the immune deficient.

The Institute deserves some kind of medieval booby prize for hysterical inhumanity. They've given testing a bad name when it should have a very, very good one. The only good thing to come out of this sad and wretched business is the reinforcement it will give the conviction held by sensible men and women that the most stringent antidiscrimination measures on behalf of the infected have become imperative.

Health protocol. The results must remain confidential between the insurer and the insured to preserve so far as possible the quality of life for someone who tests HIV-positive.

Other regulatory guidelines specify that sexual orientation may not be used as an underwriting criterion or to determine insurability. Diagnostic questions can be used to establish the presence of AIDS or ARC. Questions related to the presence of a medical condition are proper if they're not used to detect sexual orientation. Furthermore, medical questions must relate to a finite period, and demographic information regarding the applicant may not be used to establish the applicant's sexual orientation. For the purposes of rating an applicant, an insurer may impose territorial rates, but only if such rates are based upon sound actuarial principles or reasonably expected experience. And no adverse underwriting decision may be made if an applicant has innocently in the past expressed AIDS concern to a medical provider. For example, if you had been in your doctor's office, had told him you had a cold for a month, and asked "Doc, do you think it's AIDS?" and he said "no", and if an insurer got a hold of that information, it would not be permitted to draw adverse conclusions.

I've spoken with insurance department personnel responsible for monitoring and administering the policy. I'm told that problems have arisen with respect to insurers who want to ask about AIDS but not about other life-threatening diseases or signs of disease. They've been told that this does not comply with the intent of the policy and is not permissible activity in underwriting insurance under Delaware law.

Furthermore, some insurance underwriters have asked the Insurance Department whether they could put a limitation on health care payments for AIDS patients. They have been informed that it would not be within the intent of the regulations to unfairly make AIDS a suspect classification just because it's AIDS as opposed to say, cancer, which can also lead to catastrophic medical costs.

Finally, insurers have asked whether they can, upon an applicant's seeking recertification or seeking to increase his benefits, test or ask questions related to AIDS. The answer is "Yes", provided the insurer also asks about other life-threatening diseases.

As you can see from the foregoing account AIDS is an across the board problem in the administration of justice. I get AIDS questions every day, and I'm only one of many attorneys in the Department of Justice. I'm trying to acquaint my fellow attorneys about their responsibilities with respect to AIDS and what they can expect to encounter in their practices. It's a difficult process that we're going to go through for the next few years, but it's one we're going to *have* to get through. We have no choice at this point. I hope that the decisions we make with respect to AIDS are reasonable and consistent with informed medical and scientific judgment rather than fear and discrimination, and I believe that with the effort we are making to become informed, our decisions will be fair and prudent. ■

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The Legislative Posture

David J. Lyons

The informed consent and confidentiality legislation* regarding HIV related testing represents a compromise. This is not unusual as very little is done legislatively where some form of compromise is not required. AIDS legislation is no different. The AIDS crisis represents the major public health challenge of this century and reasonable minds have differed and will continue to differ on the multiplicity of complex issues that the crisis has engendered. With that in mind, I will highlight in a general way the major differences between the majority and minority view points of the AIDS Legislative Task Force with respect to informed consent and confidentiality of HIV testing.

A majority of the Task Force believed specific HIV testing informed consent guidelines had to be enacted to prevent unauthorized testing and potential misuse of the results leading to possible drastic emotional, social, and economic consequences for those tested. The minority believed that, although informed consent should be obtained before HIV testing and counseling initiated afterwards, the formality of the majority's legislative proposal would discourage physicians from requesting that a patient be tested and patients from agreeing to be tested. The legislature adopted the majority position, which specifically states the type of information that must be given for informed consent.

The minority recommended two additional exceptions to the majority's informed consent proposal: testing without consent in a pregnancy setting, when the knowledge of the mother's HIV status is considered necessary to protect the health of the mother's unborn or newborn child, and testing without consent where a health care provider's health has been threatened as a result of exposure to a patient's blood or bodily fluids in a manner known to transmit HIV.

With respect to pregnancy testing, the minority wanted to preserve a physician's right to order HIV testing of pregnant women in high risk groups even without informed consent in order to allow appropriate prenatal care. The majority believed that a women's right to direct her own medical care should not be disturbed, leaving the physician the right to refuse medical care on professional grounds. In other words, if the physician believes the test essential to ensure adequate medical care for mother and child, the physician can refer the mother elsewhere for treatment.

The minority strongly advocated a health care provider's right to unilaterally initiate testing after an accidental exposure to a patient's blood or bodily fluids in the interest of the emotional and physical well being of the provider. The majority believed little would be gained by this exception, arguing that imperfections in HIV antibody testing might leave the provider with a false sense of security if the test was negative and that the best way to ensure a provider's well being would be to have him undergo testing.

The legislature sustained the majority position on HIV testing of pregnant women leaving them with full autonomy. It should be noted, however, that the recently revised Sexually Transmitted Diseases Statute** would allow the State Board of Health to order HIV testing in a pregnancy setting. The Legislature accepted the minority position with respect to a health care provider's right to conduct HIV testing without informed consent in the case of accidental exposure to a patient's blood or blood products. However, the final definition of "in a manner known to transmit HIV" does not reference "bodily fluids" as proposed by the minority. Rather, the definition refers only to parenteral exposure to "blood or blood products", and allows the Division of Public Health to declare other possible modes of transmission.

Regarding confidentiality, the minority strongly agreed that one's HIV status, as well as all medical record information, should be protected from unauthorized disclosure. However, the minority urged that a health care provider be able to unilaterally access HIV test results when necessary to render appropriate care and treatment. The legislation as enacted adopted the majority position, leaving the patient full autonomy to decide whether a health care provider may have access to an HIV test record, absent an emergency in which the patient is incapable of giving consent. Once consent is obtained the legislation permits the dissemination of a patient's HIV status to a provider's agents or employees who have a medical need to know such information in order to provide health care.

The penalty section proposed by the majority stated that intentional or reckless violations would constitute a Class A misdemeanor. The minority objected to a criminal penalty for a violation of the Act, arguing that criminal sanctions against health care providers for violations were illogical, as it would be more appropriate to penalize those who intentionally discriminate against the HIV infected in various societal settings.

The legislature left intact civil penalty provisions, but adopted the minority's recommendation that criminal sanctions be deleted. The civil sanctions provide for liquidated damages and allow reasonable attorney's fees to successful litigants. ■

**HB 559, as amended by House Amendment Nos. 4 and 6.*

***HB 599, as amended by House Amendment Nos. 1 and 2.*

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Minority Report of the AIDS Advisory Task Force

The undersigned members of the AIDS Advisory Task Force strongly disagree with the specifics of and with the underlying assumptions implied by the Task Force's recommendations concerning informed consent and confidentiality.

The official charge given the AATF by the Division of Public Health, stated concisely in the September 1987 report of the Task Force, reads "issue recommendations as appropriate in the interest of:

a. Protecting the public health

b. Preventing the transmission of AIDS

c. Reducing unwarranted fears and misunderstandings about AIDS

d. Protecting legal and social rights of those afflicted with AIDS or otherwise infected with the AIDS virus."

Each of these four goals is worthy. They must be achieved in ways that do not sacrifice any one goal in the interests of achieving any other. Though we fully agree with the Task Force that discrimination against HIV positive individuals or against any subset of the population is odious and must be fought with legislation and education, we will not be associated with any recommendations that place anti-discrimination efforts above the interests of the public health.

The majority recommendations of the AATF are based on the assumption that protecting the legal and social rights of the HIV positive individual is a goal which must be sought at all costs. To place risk of criminal sanctions on physicians who diagnose this infection, rather than upon individuals who hysterically and intentionally discriminate against HIV positive persons, is to place this goal well above the goal of protecting the public health and the goal of preventing transmission of AIDS.

The rights of HIV positive individuals should be protected by legislation which specifies that discrimination on the basis of HIV positivity or diagnosis of ARC or AIDS, in the areas of employment, housing or education is illegal and punishable by criminal sanctions.

The burgeoning epidemic of HIV positivity, must be dealt with according to established principles of the disciplines of Public Health and Infectious Disease. To approach this disease as a purely sociological problem rather than as a serious medical problem is a tremendous mistake.

Our specific objections and recommendations with regard to this draft are the following:

Section 1. - 5.

We recommend, in the interest of consistency and completeness, that the CDC's definition of a health care worker be used here as well: "health care worker —nurses, physicians, dentists and other dental workers, optometrists, podiatrists, chiropractors, laboratory and blood bank technologists and technicians, phlebotomists, dialysis personnel, emergency health care providers (including paramedics, emergency medical technicians, law enforcement personnel, fire fighters), and others whose activities involve contact with patients, their blood or body fluids, or corpses."

Section 1 should also include the definition of the term "manner known to transmit HIV." "Parenteral exposure (for example injection through the skin) or exposure of a mucous membrane (for example, mouth, nose or eyes), to blood or blood products or body fluids. Also to include, prolonged cutaneous exposures to large amounts of blood or blood products or other exposures as may be determined by the Division of Public Health."

Section 2. C. Item 2.

Testing must be allowed for purposes of research and this testing should be anonymous. However, it is standard practice for the identity of research subjects to be retrievable by the researcher if the well being of the subject is in jeopardy. Specifically, the last phrase of Item #2 "and may not be retrieved by the researcher," should be deleted. As treatment becomes available to prolong life and improve the quality of life in HIV infection, researchers must be permitted to break the codes and to retrieve the identity of the HIV positive subject so that those subjects may avail themselves of such treatment.

Although it is unprecedented to require by law informed consent prior to diagnostic testing for any sexually transmitted disease or for any disease associated with immune deficiency, the fear of misuse of test results has occasioned wide public sentiment in favor of informed consent for HIV testing. Such informed consent as is recommended by the AATF is so cumbersome and convoluted that it will frighten many individuals into refusing to be tested.

A patient's consent should be obtained prior to HIV testing. The patient should know the test that is being done, the purpose of the test, the potential uses of the test results and the manner in which the test is being performed. Appropriate counseling should also be given. The much more involved "informed consent" recommended by the AATF will discourage the physician from requesting the patient to be tested, and will discourage patients from agreeing to be tested once asked. These two factors combined could lead to delay in timely diagnosis, treatment and institution of behavior that will decrease the risk of transmission of the disease. (Early diagnosis of the HIV infection may be particularly important for women in their child bearing years. Fifty percent of the babies born to HIV positive mothers will be infected, and the pregnancy itself can accelerate appearance of symptomatic immune deficiency in the mother.)

If informed consent should become state law, there are two exceptions that mut be added to those listed in Section C of the final draft. (Both of these exceptions were part of the original recommendations of the AATF. The deletion by more radical elements in the Task Force of exceptions for testing in the setting of pregnancy and of exposure of the health care worker to

(Continued on next page)

Minority Report
(continued)

potentially infectious material is irresponsible, and is a primary reason for the need for this minority report.)

HIV testing of a patient should be permitted when "the health of a health care worker has been threatened during the course of the health care workers duties, as a result of exposure to blood or body fluids of the patient in a manner known to transmit HIV. Most health care workers do not and should not have any choice about which patients receive their services. Although health care workers are seldom at high risk of being infected with HIV, the health care worker should have the right to demand HIV testing of any patient to whom they have had significant exposure of blood or body fluids.

We must be mindful also of the fact that there is nationwide, an enormous shortage of nursing and other health care personnel. The exclusion of this item from exceptions to need for informed consent would likely worsen our nursing crisis just at a period in time when the needs of babies born with HIV infection and of adults becoming symptomatic with ARC and AIDS and HIV encephalopathy could place a greater than ever burden upon the state's health care systems.

Exception must also be made "when knowledge of such test results is necessary to protect the health of the patient's unborn or newborn child." HIV antibody testing should be an important part of prenatal testing for women in high risk groups. (Since the definition of "high risk group" continues to broaden and now includes, among others, all sexually active individuals; and as more reliable HIV tests are developed, HIV testing may become a part of routine prenatal care of all pregnant women.)

Section 3. - Confidentiality.

We strongly agree that a patient's confidentiality is to be respected with regard to HIV status as well as to all contents of his medical record.

We would delete the description "legally effective" from the definition of release of test results in Item #2 under Section 3. A. Inclusion of these words would require the health care worker to make a judgement on the legality of the preparation of the release. This is a judgement that the health care worker is not qualified to make. Item #2 should read "any person authorized by the patient or the patient's legal guardian."

Exceptions #3 and #4 are very important. We would alter Item #4 only by deleting "emergency" as a definition of the appropriate care and treatment.

Section 4.

This entire section should be deleted.

It has never before been a policy in the United States to make a criminal offense of the performance of a diagnostic blood test for an infectious disease or for any other disease. Sufficient avenues for redress of grievance are presently available through the civil justice system.

More importantly, the purpose of this section being to protect HIV positive individuals from discrimination, the emphasis is entirely misplaced. Criminal sanctions should be taken against those employers, landlords or educators who are guilty of the discrimination, not against the health care workers who diagnose the infection and care for the patient. ■

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